

1 **TERMS OF REFERENCE AND PROFILE FOR MEMBERS OF**  
 2 **GROUPS OF EXPERTS AND WORKING PARTIES**

3 *The terms of reference and profiles shown below have been drafted by the Presidium to aid national*  
 4 *authorities when making proposals for appointment. In addition to the profile described, national*  
 5 *authorities should also ensure that the experts proposed are available to attend meetings and are prepared*  
 6 *to draft and/or verify monographs and general chapters and when required in the profile, have access to a*  
 7 *laboratory for experimental verifications.*

8 *Each group of experts and working party will advise the Commission and other groups of experts and*  
 9 *working parties where relevant, according to their expertise and contribute to the maintenance of*  
 10 *the relevant technical guide where appropriate.*

11 *The chairs of the following groups are members of the PCM working party: Groups 6, 7, 9, 10A/B/C/D, 11,*  
 12 *13H, 14, 17, P4 and MG WP. The chairs of the other groups of experts and working parties may be invited*  
 13 *on an ad hoc basis, depending on the agenda. The Chair of the Ph. Eur. Commission is chairing the PCM and*  
 14 *ROP working parties.*

15 *In the context of this document, the term “regulatory authority” encompasses OMCLs, licensing authorities,*  
 16 *NPAs and/or inspectorates.*

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**1 Group of Experts No. 1 (Microbiology)****2 Terms of reference**

- 3 • Drafting and revision of general chapters in the field of microbiology
- 4 • Advising the Commission on questions related to microbiological quality, including quality
- 5 attributes in monographs drafted by other groups of experts and working parties
- 6 • International harmonisation of general chapters in the field of microbiology
- 7 • Drafting and revision of general chapters in the field of alternative microbiological methods (the so
- 8 called “rapid methods”)
- 9 • Assessment of proposed examples in view of their inclusion in document: “*Examples of validation*
- 10 *protocols for alternative microbiological methods according to chapter 5.1.6*”, to be published on
- 11 the EDQM website.

**12 Profile for experts**

- 13 • Current expertise in microbiological analytical methods, related to quality control of active
- 14 substances, excipients and medicinal products and in development of control methods
- 15 • Several years of experience in one or more of the following fields
- 16 ○ Microbiological quality control in a pharmaceutical manufacturing setting, in a hospital
- 17 environment or in an independent testing laboratory
- 18 ○ Market surveillance of microbiological quality in a regulatory authority
- 19 ○ Assessment of the relevant parts of applications for marketing authorisation
- 20 ○ Development of microbiological control methods in a research and development
- 21 environment

**22 Profile for ad-hoc specialists on alternative microbiological methods (please indicate this field of expertise**  
**23 on the nomination form, if applicable)**

- 24 • Current expertise in microbiological analytical methods, related to quality control of active
- 25 substances, excipients and medicinal products and in development of control methods
- 26 • Several years of experience in one or more of the following fields:
- 27 ○ Validation of alternative microbiological methods in a pharmaceutical manufacturing
- 28 setting, in a hospital environment or in an independent testing laboratory
- 29 ○ Market surveillance of microbiological quality in a regulatory authority using alternative
- 30 microbiological methods
- 31 ○ Assessment of the relevant parts of applications for marketing authorisation
- 32 ○ Development of alternative microbiological control methods in a research and
- 33 development environment

**34 Group of Experts No. 6 (Biological and Biotechnological products)****35 Terms of reference**

- 36 • Drafting and revision of texts in the field of biological products, biotechnological products, including
- 37 glycoproteins, and synthetic peptides
- 38 • International harmonisation of general chapters in the field of biological products

**39 Profile for experts**

- 40 • Current expertise in quality control of biological products, biotechnological products (including
- 41 glycoproteins), peptides

- 1 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
2 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
3 procedures and drafting of texts
- 4 • Several years of experience in one or more of the following fields:
- 5 ○ Quality control of biological products, biotechnological products, including glycoproteins  
6 or of peptides in a pharmaceutical manufacturing setting
- 7 ○ Quality control in a regulatory authority
- 8 ○ Quality control of biological or biotechnological products, including glycoproteins, or of  
9 peptides in an independent testing laboratory
- 10 ○ Development of analytical procedures for control of biological or biotechnological  
11 products, including glycoproteins or of peptides in a research and development  
12 environment
- 13 ○ Analytical procedure development and verification in a regulatory authority
- 14 ○ Assessment of the relevant parts of application for marketing authorisation of biological  
15 and biotechnological products within a medicines agency

#### 16 **Group of Experts No. 6B (Human Plasma and Plasma Products)**

##### 17 *Terms of reference*

- 18 • Drafting and revision of texts in the field of blood products

##### 19 *Profile for experts*

- 20 • Current expertise in the field of blood products, notably related to their quality control and  
21 development of analytical procedures for control of these products
- 22 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
23 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
24 procedures and drafting of texts
- 25 • Several years of experience in one or more of the following fields:
- 26 ○ Quality control of blood products in a pharmaceutical or bulk manufacturing setting
- 27 ○ Batch release or market surveillance of Human Blood, Plasma and Plasma Products in a  
28 regulatory authority
- 29 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
30 medicines agency
- 31 ○ Quality control of blood products in an independent testing laboratory
- 32 ○ Analytical procedure development and verification in a regulatory authority
- 33 ○ Development of analytical procedures for control of Human Plasma and Plasma Products  
34 in a research and development environment

#### 35 **Group of Experts No. 7 (Antibiotics)**

##### 36 *Terms of reference*

- 37 • Drafting and revision of texts in the field of antibiotic active substances and medicinal products  
38 containing such substances
- 39 • Provision of expertise in the field of antibiotics to Group 17 where relevant

##### 40 *Profile for experts*

- 41 • Current expertise in the fields of antibiotics
- 42 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
43 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
44 procedures and drafting of texts

- 1       • Several years of experience in one or more of the following fields:
- 2           ○ Quality control of antibiotics in a pharmaceutical manufacturing setting
- 3           ○ Quality control of antibiotics in a bulk manufacturing setting
- 4           ○ Quality control of antibiotics in a regulatory authority
- 5           ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 6           medicines agency
- 7           ○ Quality control of antibiotics in an independent testing laboratory
- 8           ○ Development of analytical procedures for control of antibiotics in a research and
- 9           development environment
- 10          ○ Analytical procedure development and verification in a regulatory authority

## 11 **Group of experts No. 9 (Inorganic Chemistry)**

### 12 *Terms of reference*

- 13       • Drafting and revision of monographs in the field of inorganic substances
- 14       • International harmonisation of monographs

### 15 *Profile for experts*

- 16       • Current expertise in pharmaceutical analytical procedures, related to quality control of inorganic
- 17       substances and in development of such analytical procedures
- 18       • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 19       inclusion in monographs, for example ICP and/or AAS. **Essential:** Active involvement in laboratory
- 20       verification of analytical procedures and drafting of texts.
- 21       • Several years of experience in one or more of the following fields:
- 22           ○ Quality control of inorganic substances in a pharmaceutical or bulk manufacturing setting
- 23           ○ Market surveillance of quality in a regulatory authority
- 24           ○ Pharmaceutical quality control in an independent testing laboratory
- 25           ○ Development of analytical procedures for control of inorganic substances in a research and
- 26           development environment
- 27           ○ Analytical procedure development and verification in a regulatory authority

## 28 **Group of Experts No. 9G (Medicinal Gases)**

### 29 *Terms of reference*

- 30       • Drafting and revision of texts in the field of medicinal gases

### 31 *Profile for experts*

- 32       • Current expertise in the field of medicinal gases
- 33       • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 34       inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 35       procedures and drafting of texts
- 36       • Several years of experience in one or more of the following fields:
- 37           ○ Quality control of medicinal gases in a pharmaceutical manufacturing, hospital or industrial
- 38           setting
- 39           ○ Quality control in a regulatory authority
- 40           ○ Development of analytical procedures for control of medicinal gases in a research and
- 41           development environment

1 **Group of Experts No. 10A/B/C/D (Organic chemistry – synthetic and semi-synthetic substances)**

2 *Terms of reference*

- 3 • Drafting and revision of monographs in the field of synthetic and semi-synthetic organic substances  
4 and medicinal products containing such substances  
5 • If needed, provide expertise in the field of organic chemistry to Group 17

6 *Profile for experts*

- 7 • Current expertise in pharmaceutical analytical procedures, related to quality control of synthetic  
8 and semi-synthetic organic substances and/or medicinal products containing such substances and  
9 in development of such analytical procedures  
10 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
11 inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical  
12 procedures and drafting of texts.  
13 • Several years of experience in one or more of the following fields:  
14 ○ Quality control in a pharmaceutical manufacturing setting  
15 ○ Quality control of synthetic and semi-synthetic organic products and/or medicinal products  
16 containing such substances in a bulk manufacturing setting  
17 ○ Market surveillance of quality in a regulatory authority  
18 ○ Pharmaceutical quality control of synthetic and semi-synthetic organic substances and/or  
19 medicinal products containing such substances, in an independent testing laboratory  
20 ○ Development of analytical procedures for control of synthetic and semi-synthetic organic  
21 substances and/or medicinal products containing such substances in a research and  
22 development environment  
23 ○ Group 10D: development of analytical procedures for amino-acids  
24 ○ Analytical procedure development and verification in a regulatory authority

25 **Group of Experts No. 11 (Organic chemistry – natural, semi-synthetic and synthetic substances)**

26 *Terms of reference*

- 27 • Drafting and revision of monographs in the field of natural, semi-synthetic and synthetic organic  
28 substances and medicinal products containing such substances  
29 • Provision of expertise in the field of organic chemistry to the Group 17 where relevant

30 *Profile for experts*

- 31 • Current expertise in pharmaceutical analytical procedures, related to quality control of natural,  
32 semi-synthetic and synthetic organic substances and/or medicinal products containing such  
33 substances, and in development of such analytical procedures  
34 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
35 inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical  
36 procedures and drafting of texts.  
37 • Several years of experience in one or more of the following fields:  
38 ○ Quality control in a pharmaceutical manufacturing setting  
39 ○ Quality control of natural, semi-synthetic and synthetic organic substances and/or  
40 medicinal products containing such substances in a bulk manufacturing setting  
41 ○ Market surveillance of quality in a regulatory authority  
42 ○ Pharmaceutical quality control in an independent testing laboratory  
43 ○ Development of analytical procedures for control of natural, semi-synthetic and synthetic  
44 organic substances and/or medicinal products containing such substances in a research and  
45 development environment

- 1           ○ Analytical procedure development and verification in a regulatory authority

2   **Group of Experts No. 12 (Dosage forms and pharmaceutical technical procedures)**

3   *Terms of reference*

- 4       • Drafting and revision of dosage form monographs and pharmaceutical technical procedures
- 5       • Maintenance of dosage form related International Harmonisation topics such as:
- 6           ○ uniformity of dosage units
- 7           ○ dissolution
- 8           ○ disintegration
- 9       • Particulate contamination: visible and sub-visible particles
- 10      • Provision of expertise in the field of pharmaceutical technology to other groups where relevant

11 *Profile for experts*

- 12      • Current expertise in pharmaceutical development and analytical procedures used for in-process
- 13      control and end product testing of pharmaceutical preparations, in the relevant specialities defined
- 14      in the terms of reference
- 15      • Several years of experience in one or more of the following fields:
- 16           ○ Development and quality control of pharmaceutical preparations in an industrial setting
- 17           ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 18           medicines agency
- 19           ○ Development of analytical procedures for testing of pharmaceutical preparations in a
- 20           research and development environment
- 21           ○ Analytical procedure development and verification in a regulatory authority

22 **Group of Experts No. 13A/B (Herbal Drugs and Herbal Drug Preparations)**

23 *Terms of reference*

- 24      • Drafting and revision of texts in the field of herbal drugs and herbal drug preparations

25 *Profile for experts*

- 26      • Current expertise in pharmaceutical analytical procedures, related to quality control of herbal drugs
- 27      and herbal drug preparations and in development of such analytical procedures
- 28      • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 29      inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 30      procedures and drafting of texts.
- 31      • Several years of experience in one or more of the following fields:
- 32           ○ Quality control of herbal drugs and herbal drug preparations in a pharmaceutical
- 33           manufacturing or bulk manufacturing setting
- 34           ○ Market surveillance of quality of herbals in a regulatory authority
- 35           ○ Assessment of the relevant parts of applications for marketing authorisation of herbal
- 36           medicinal products within a medicines agency
- 37           ○ Pharmaceutical quality control of herbal drugs and herbal drug preparations in an
- 38           independent testing laboratory
- 39           ○ Development of analytical procedures for control of herbal drugs in a research and
- 40           development environment
- 41           ○ Analytical procedure development and verification in a regulatory authority

1 **Group of Experts No. 13H (Fatty oils and derivatives, polymers)**

2 *Terms of reference*

- 3 • Drafting and revision of texts in the field of:
- 4 ○ surfactants
  - 5 ○ fatty oils, fats and waxes
  - 6 ○ fatty acids, fatty alcohols and their esters/ethers
  - 7 ○ macrogols, macrogol derivatives and other polymers (e.g. carbomers)
  - 8 ○ paraffins
- 9 • International Harmonisation of the relevant monographs

10 *Profile for experts*

- 11 • Current expertise in pharmaceutical analytical procedures, related to quality control in the relevant
- 12 specialities defined in the terms of reference
- 13 • Member of a regulatory authority, universities or the pharmaceutical/chemical industries
- 14 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 15 inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 16 procedures and drafting of texts
- 17 • Several years of experience in one or more of the following fields:
- 18 ○ Quality control in a pharmaceutical manufacturing setting
- 19 ○ Quality control of fats etc. in a bulk manufacturing setting
- 20 ○ Market surveillance of quality in a regulatory authority
- 21 ○ Pharmaceutical quality control of fats etc. in an independent testing laboratory
- 22 ○ Development of analytical procedures for control of fats etc. in a research and
- 23 development environment
- 24 ○ Analytical procedure development and verification in a regulatory authority

25 **Group of Experts No. 14 (Radiopharmaceutical Preparations)**

26 *Terms of reference*

- 27 • Drafting and revision of texts in the field of radiopharmaceutical preparations

28 *Profile for experts*

- 29 • Current expertise in pharmaceutical analytical procedures, related to quality control of
- 30 radiopharmaceutical preparations and in development of such analytical procedures
- 31 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 32 inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 33 procedures and drafting of texts
- 34 • Several years of experience in one or more of the following fields:
- 35 ○ Quality control of radiopharmaceutical preparations in a pharmaceutical manufacturing
- 36 setting or in a hospital
- 37 ○ Market surveillance of quality of radiopharmaceutical preparations in a regulatory
- 38 authority
- 39 ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 40 medicines agency
- 41 ○ Pharmaceutical quality control of radiopharmaceutical preparations in an independent
- 42 testing laboratory
- 43 ○ Analytical procedure development and verification in a regulatory authority

**1 Group of Experts No. 15 (Human Vaccines and Sera)****2 Terms of reference**

- 3 • Drafting and revision of texts in the field of vaccines and sera for human use
- 4 • Drafting and revision of monographs in the field of botulinum toxins

**5 Profile for experts**

- 6 • Current expertise in analytical procedures, related to quality control of vaccines and sera for human  
7 use and in development of such analytical procedures
- 8 • Several years of experience in one or more of the following fields:
  - 9 ○ Quality control of vaccines and sera for human use in a pharmaceutical manufacturing  
10 setting
  - 11 ○ Batch release and market surveillance of quality of vaccines and sera for human use in a  
12 regulatory authority
  - 13 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
14 medicines agency
  - 15 ○ Quality control of vaccines and sera for human use in an independent testing laboratory

**16 Profile for botulinum toxins ad hoc specialists (please indicate this field of expertise on the nomination form,  
17 if applicable)**

- 18 • Current expertise in analytical procedures for the control of botulinum toxins and in development  
19 of such analytical procedures
- 20 • Several years of experience in one or more of the following fields:
  - 21 ○ Quality control of botulinum toxins in a pharmaceutical manufacturing setting
  - 22 ○ Batch release or market surveillance of quality of botulinum toxins in a regulatory authority
  - 23 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
24 medicines agency
  - 25 ○ Pharmaceutical quality control of botulinum toxins in an independent testing laboratory
  - 26 ○ Development of analytical procedures for control of botulinum toxins in a research and  
27 development environment

**28 Group of Experts No. 15V (Veterinary Vaccines and Sera)****29 Terms of reference**

- 30 • Drafting and revision of texts in the field of immunological veterinary medicinal products (IVMP)

**31 Profile for experts**

- 32 • Current expertise in suitable standards for IVMP, in analytical procedures related to quality control  
33 of these products and in development of such analytical procedures
- 34 • Several years of experience in one or more of the following fields:
  - 35 ○ Quality control of IVMP in a regulatory authority
  - 36 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
37 medicines agency
  - 38 ○ Batch release and market surveillance of quality in a regulatory authority
  - 39 ○ Development of analytical procedures for control of IVMP in a research and development  
40 environment
- 41 • Industry representatives are normally not appointed to Group of Experts No. 15V. They may be  
42 invited to contribute to elaboration of texts during hearings organised on a case-by-case basis by  
43 the Secretariat.

1 **Group of Experts No. 16 (Plastic materials, plastic containers and closures)**

2 *Terms of reference*

- 3 • Drafting and revision of texts in the field of plastic materials, plastic containers and closures

4 *Profile for experts*

- 5 • Current expertise in the fields covered by the terms of reference
- 6 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 7 inclusion in texts, **Essential:** Active involvement in laboratory verification of analytical procedures
- 8 and drafting of texts
- 9 • Several years of experience in one or more of the following fields:
- 10 ○ Quality control of plastic materials, plastic containers and closures
- 11 - in a pharmaceutical manufacturing setting,
- 12 - in a regulatory authority or
- 13 - in an independent testing laboratory
- 14 ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 15 medicines agency
- 16 ○ Analytical procedure development and verification in a regulatory authority

17 **Group of Experts 17 (Medicinal products containing chemically defined active substances)**

18 *Terms of reference*

- 19 • Drafting and revision of monographs on medicinal products containing chemically defined active
- 20 substances (especially in case of a dosage form not yet covered by the technical guide)
- 21 • Drafting of monographs on active substances contained in these medicinal products if
- 22 the monographs are being elaborated in parallel and if deemed appropriate;
- 23 • Provision of expertise to other groups where relevant

24 *Profile for experts*

- 25 • Current expertise in pharmaceutical analytical procedures, related to quality control of medicinal
- 26 products containing chemically defined active substances and in development of such analytical
- 27 procedures
- 28 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 29 inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 30 procedures and drafting of texts.
- 31 • Several years of experience in one or more of the following fields:
- 32 ○ Development and verification of analytical procedures
- 33 ○ Quality control or development of medicinal products containing chemically defined active
- 34 substances
- 35 ○ Market surveillance testing
- 36 ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 37 medicines agency

38 **Group of Experts P4**

39 *Terms of reference*

- 40 • Drafting and revision of monographs in the field of single-source active substances, excipients and
- 41 medicinal products with chemically defined active substances

42 *Profile for experts*

- 43 • Current expertise in pharmaceutical analytical procedures, related to quality control of active
- 44 substances, excipients and medicinal products (with chemically defined active substances), and in
- 45 development of such analytical procedures

- 1 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
2 inclusion in monographs or access to licensing files, **Essential:** Active involvement in laboratory  
3 verification of analytical procedures and drafting of texts.
- 4 • Several years of experience in one or more of the following fields:
- 5 ○ Assessment of the relevant parts of applications for marketing authorisation
- 6 ○ Market surveillance studies in a regulatory authority
- 7 ○ Analytical procedure development and verification in a regulatory authority
- 8 • Group P4 is restricted to regulators from Ph. Eur. Member states however industry representatives  
9 may be invited to contribute by submission of data and interaction with the group via  
10 the Secretariat

### 11 **ALG Working Party (Allergens)**

#### 12 *Terms of reference*

- 13 • Drafting and revision of texts in the field of allergen products

#### 14 *Profile for experts*

- 15 • Current expertise in pharmaceutical analytical procedures, related to quality control of allergens  
16 and in development of such analytical procedures
- 17 • Several years of experience in one or more of the following fields:
- 18 ○ Quality control of allergen products in a pharmaceutical manufacturing setting
- 19 ○ Market surveillance of quality of allergen products in a regulatory authority
- 20 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
21 medicines agency
- 22 ○ Pharmaceutical quality control of allergen products in an independent testing laboratory
- 23 ○ Development of analytical procedures for control of allergens in a research and  
24 development environment

### 25 **ALU Working Party (Aluminium in parenteral nutrition solutions)**

#### 26 *Terms of reference*

- 27 • Drafting of general chapter on aluminium in parenteral nutrition solutions

#### 28 *Profile for experts*

- 29 • Current expertise in parenteral nutrition solutions, notably related to quality and toxicological  
30 assessment of aluminium content, or in aluminium in parenteral preparations,
- 31 • Several years of experience in one or more of the following fields
- 32 ○ Quality control of parenteral nutrition solutions and/or parenteral preparations
- 33 ○ Assessment of the relevant parts of applications for marketing authorisation
- 34 ○ Development and verification of analytical procedures for control of aluminium in  
35 parenteral preparations and/or parenteral nutrition solutions
- 36 ○ Market surveillance of quality of parenteral preparations and/or parenteral nutrition  
37 solutions in a regulatory authority
- 38 ○ Preparation and administration of parenteral nutrition solutions or of parenteral  
39 preparations in a clinical setting

1 **AQbD Working Party (Analytical quality by design)**

2 *Terms of reference*

- 3 • Assess the feasibility and impact of incorporating analytical procedures developed using  
4 the concepts of analytical quality by design (aQbD) in Ph. Eur. monographs.
- 5 • Advise the Commission and expert groups on appropriate elaboration/revision strategies for  
6 incorporating such analytical procedures in monographs.
- 7 • Identify verification and revision approaches for analytical procedures developed using aQbD.
- 8 • Co-operation and consultation with other groups of experts and working parties in charge of  
9 the elaboration and revision of monographs, where relevant.

10 *Profile for experts*

- 11 • Current expertise in the development of analytical procedures for the assessment of the quality of  
12 active substances and medicinal products
- 13 • Knowledge of pharmacopoeial monograph development
- 14 • Several years of experience in one or more of the following fields:
- 15 ○ Development, validation and verification of analytical procedures, if possible applying  
16 aQbD concepts
- 17 ○ Market surveillance testing
- 18 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
19 medicines agency, if possible with experience of assessing applications that used aQbD  
20 concept.

21 **BACT Working Party (Bacteriophages)**

22 *Terms of reference*

- 23 • To elaborate the general chapter 'Phage therapy active substances and medicinal products for  
24 human and veterinary use'.

25 *Profile for experts*

- 26 • Current expertise in analytical procedures related to quality control of bacteriophages and in  
27 development of such analytical procedures
- 28 • Several years of experience in one or more of the following fields:
- 29 ○ Quality control of bacteriophages in a manufacturing setting
- 30 ○ Preparation and administration of bacteriophages manufactured in a non-industrial way  
31 but of a quality compatible with clinical use (compassionate access)
- 32 ○ Development of bacteriophages for clinical use
- 33 ○ Analytical procedure development and verification in a regulatory authority

34 **BET Working Party (Bacterial Endotoxin Test)**

35 *Terms of reference*

- 36 • Drafting and revision of general chapters in the field of bacterial endotoxins
- 37 • Advising the Commission and expert groups on appropriate analytical procedures for the detection  
38 of bacterial endotoxins or pyrogens in substances for pharmaceutical use or pharmaceutical  
39 preparations.
- 40 • Drafting and revision of general chapters in the field of the monocyte activation tests (MAT)
- 41 • International Harmonisation of the relevant texts

42 *Profile for experts*

- 43 • Current expertise in practical application of the bacterial endotoxin test and/or MAT

- 1       • Several years of experience in one or more of the following fields:
- 2           ○ Quality control of parenteral preparations, active substances and/or excipients in a
- 3           pharmaceutical manufacturing setting
- 4           ○ Market surveillance of quality in a regulatory authority
- 5           ○ Pharmaceutical quality control in an independent testing laboratory
- 6           ○ Development of analytical procedures for bacterial endotoxin testing and/or MAT in a
- 7           research and development environment
- 8           ○ Analytical procedure development and verification in a regulatory authority
- 9       • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 10       inclusion in monographs
- 11

## 12 **BSR Working Party (Bovine serum)**

### 13 *Terms of reference*

- 14       • Maintenance of the monograph *Bovine serum* (2262)
- 15       • Drafting and revision of other texts pertaining to bovine sera as appropriate

### 16 *Profile for experts*

- 17       • Current expertise in analytical procedures related to quality control of bovine sera and in
- 18       development of such analytical procedures
- 19       • Several years of experience in one or more of the following fields:
- 20           ○ Quality control of bovine serum in a pharmaceutical manufacturing setting
- 21           ○ Market surveillance of quality in a regulatory authority
- 22           ○ Assessment of the relevant parts of applications for marketing authorisation within a
- 23           medicines agency
- 24           ○ Pharmaceutical quality control in an independent testing laboratory
- 25           ○ Development of analytical procedures for control of bovine serum in a research and
- 26           development environment

## 27 **CE Working Party (Capillary Electrophoresis)**

### 28 *Terms of reference*

- 29       • Revision of the chapter 2.2.47 *Capillary electrophoresis*
- 30       • Advising the Commission on questions related to capillary electrophoresis in monographs drafted
- 31       by other groups of experts and working parties
- 32       • International Harmonisation of the relevant texts

### 33 *Profile for experts*

- 34       • Current expertise in *Capillary electrophoresis* techniques
- 35       • Several years of experience in the following fields:
- 36           ○ Quality control of active substances, excipients and medicinal products, using capillary
- 37           electrophoresis techniques, in a pharmaceutical manufacturing setting, in a regulatory
- 38           authority or in any other testing laboratory
- 39           ○ Development of analytical procedures using capillary electrophoresis for control of active
- 40           substances, excipients and medicinal products in a research and development environment
- 41           or at university
- 42           ○ Access to laboratory facilities for verification and validation of analytical procedures
- 43           proposed for inclusion in monographs **Essential:** Active involvement in laboratory
- 44           verification of analytical procedures and drafting of texts

## 1 **CEL Working Party (Cellulose)**

### 2 *Terms of reference*

- 3 • Drafting and revision of monographs on cellulose and cellulose derivatives
- 4 • International harmonisation of monographs on cellulose and cellulose derivatives

### 5 *Profile for experts*

- 6 • Current expertise in analytical procedures for cellulose and cellulose derivatives and in  
7 development of such analytical procedures
- 8 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
9 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
10 procedures and drafting of texts.
- 11 • Several years of experience in one or more of the following fields:
  - 12 ○ Quality control of cellulose and cellulose derivatives in a pharmaceutical or other industrial  
13 manufacturing setting
  - 14 ○ Market surveillance of quality of cellulose and cellulose derivatives in a regulatory authority
  - 15 ○ Quality control of cellulose and cellulose derivatives in a regulatory authority
  - 16 ○ Development of analytical procedures for control of cellulose and cellulose derivatives in a  
17 research and development environment
  - 18 ○ Analytical procedure development and verification in a regulatory authority

## 19 **cMEP Working Party (certified review of microbiological methods per the European Pharmacopoeia)**

### 20 *Terms of reference*

- 21 • Support the refinement of the scheme (see [PA/PH/SG \(26\) 13](#)), including:
  - 22 ○ Paper exercise based on the feedback gathered during the opportunity study and the early  
23 technical taskforce
  - 24 ○ Refinement of the scope and drafting of the certified review concept for alternative  
25 microbiological methods, covering validation and comparability to Ph. Eur. reference  
26 methods (and excluding product-specific validation and comparability)
  - 27 ○ Draft proposal of the technical and operational framework, including guidance for  
28 applicants, templates of data package needed for the review, and the system way-of-  
29 working
- 30 • Execute a proof-of-concept exercise (preferably on a well-known alternative analytical method and  
31 an equipment already used for an approved product) in order to test the proposed concept, identify  
32 scientific and practical bottlenecks and propose remedies ahead of a pilot phase.
- 33 • Consultation with relevant Ph. Eur. groups (e.g. Group 1, CTP, GTP) and with stakeholders (e.g. via  
34 targeted hearings/workshops) when required

### 35 *Profile for experts*

- 36 • Current expertise in microbiological analytical methods and/or analytical validation relevant to  
37 the development, implementation or assessment of alternative microbiological methods
- 38 • Several years of recent experience in one or more of the following fields:
  - 39 ○ Development, implementation (incl. validation and comparability) of alternative  
40 microbiological methods in industry or contract laboratories (method implementation,  
41 change control, batch release, troubleshooting)
  - 42 ○ Practical microbiological QC experience in manufacturing or independent testing  
43 laboratories (diverse matrices, large organism panels)
  - 44 ○ Assessment of validation and comparability packages for relevant quality dossiers and  
45 familiarity with rapid methods, sterility, bioburden, in a competent authority or OMCL
  - 46 ○ Consultancy with substantial experience in the implementation or filing of alternative  
47 microbiological methods

- 1           ○ Development and maintenance of alternative microbiological equipment (principle,  
2           hardware, software/algorithms, versioning, primary validation, comparability, data  
3           collection, awareness of method limitations and challenges, understanding of user needs)
- 4       • Knowledge of Ph. Eur. chapter 5.1.6 (and/or 2.6.27) as well as other relevant texts (incl. 2.6.1,  
5       2.6.12, 2.6.13, 2.6.7, 2.6.21)
- 6       • Ability to contribute constructively to the project, including participation in consensus drafting and  
7       review of working documents

#### 8 *Profile for ad hoc specialists*

- 9       • Statistician specialised in microbiological validation and comparability
- 10      • ATMP / short shelf-life product specialist with knowledge of rapid sterility and time-critical  
11      constraints, low-volume sampling, and matrix effects specific to cell-based/short-shelf-life  
12      products, experience with tests with long analytical time (e.g. sterility, mycoplasma) and their  
13      alternatives methods
- 14      • Regulator experienced in the assessment of the alternative microbiological methods parts of  
15      applications for marketing authorisation in a competent authority or OMCL
- 16      • Technology/method specialist (e.g. equipment supplier) with full knowledge of method  
17      principle/hardware/software, method limitations and challenges

#### 18 **CRB Working Party (Carbohydrates)**

##### 19 *Terms of reference*

- 20      • Drafting and revision of monographs in the field of carbohydrates
- 21      • International harmonisation of monographs

##### 22 *Profile for experts*

- 23      • Current expertise in pharmaceutical analytical procedures, related to quality control of  
24      carbohydrates and in development of such analytical procedures
- 25      • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
26      inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
27      procedures and drafting of texts.
- 28      • Several years of experience in one or more of the following fields:
  - 29          ○ Quality control in a pharmaceutical or bulk manufacturing setting
  - 30          ○ Market surveillance of quality in a regulatory authority
  - 31          ○ Pharmaceutical quality control in an independent testing laboratory
  - 32          ○ Development of analytical procedures for control of carbohydrates in a research and  
33          development environment
  - 34          ○ Analytical procedure development and verification in a regulatory authority

#### 35 **CST Working Party (Chromatographic separation techniques)**

##### 36 *Terms of reference*

- 37      • Revision of chapters on chromatographic separation (e.g. 2.2.28, 2.2.29, 2.2.30, 2.2.46)
- 38      • Advising the Commission on questions related to chromatographic separation techniques in  
39      monographs drafted by other groups of experts and working parties
- 40      • Co-operation with other groups of experts and working parties which use chromatographic  
41      separation techniques where relevant

##### 42 *Profile for experts*

- 43      • Current expertise in chromatographic separation techniques
- 44      • Several years of experience in one or more of the following fields:

- 1 ○ Chromatographic quality control of active substances and/or excipients in a pharmaceutical
- 2 manufacturing setting
- 3 ○ Development of chromatographic analytical procedures for control of active substances,
- 4 excipients and medicinal products in a research and development environment
- 5 ○ Market surveillance of quality in a regulatory authority
- 6 ○ Pharmaceutical quality control in an independent testing laboratory

## 7 **CTP Working Party (Cell Therapy Products)**

### 8 *Terms of reference*

- 9 • Drafting and revision of texts in the field of cell-based preparations
- 10 • Maintaining regular exchanges to ensure coordination of approaches with the GTP Working Party
- 11 in relevant areas

### 12 *Profile for experts*

- 13 • Current expertise in analytical procedures related to the development and quality control of cell
- 14 therapy products and/or tissue-engineered products and/or to the quality control of tissues for
- 15 human use
- 16 • Several years of experience in one or more of the following fields:
  - 17 ○ Development of cell therapy products and/or tissue-engineered products
  - 18 ○ Quality control of cell therapy products and/or tissue-engineered products in a
  - 19 pharmaceutical manufacturing setting or in a hospital environment and/or microbiological
  - 20 control of tissues and organs used for human transplantation
  - 21 ○ Assessment of applications for marketing authorisation of cell therapy and/or tissue-
  - 22 engineered products
  - 23 ○ Market surveillance of the quality of cell therapy products, tissue-engineered products
  - 24 and/or tissues and organs used for human transplantation in a regulatory authority
  - 25 ○ Pharmaceutical quality control in an independent testing laboratory
  - 26 ○ Development of analytical procedures (e.g. microbiological procedures) to control cell
  - 27 therapy products and/or tissue-engineered products and/or tissues and organs used for
  - 28 human transplantation in a research and development environment

## 29 **DIA Working party (Dialysis)**

### 30 *Terms of reference*

- 31 • Drafting and revision of texts in the field of preparations for dialysis

### 32 *Profile for experts*

- 33 • Current expertise in the field of preparations for dialysis
- 34 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 35 inclusion in monographs
- 36 • Several years of experience in one or more of the following fields:
  - 37 ○ Manufacture and/or quality control of preparations for dialysis in a pharmaceutical
  - 38 manufacturing setting or in a hospital
  - 39 ○ Quality control of preparations for dialysis in a regulatory authority
  - 40 ○ Assessment of the relevant parts of applications for marketing authorisation within a
  - 41 medicines agency
  - 42 ○ Quality control of preparations for dialysis in an independent testing laboratory
  - 43 ○ Analytical procedure development and verification in a regulatory authority

## 1 **EDSForm Working Party (European drug shortages Formulary)**

### 2 *Terms of reference*

- 3 • Establishment and maintenance of the CD-P-PH & EPC approved framework for the European Drug  
4 Shortages Formulary describing the following items:
  - 5 ○ Criteria and guidelines for the selection, prioritisation and evaluation of appropriate  
6 pharmaceutical preparations from national formularies and other appropriate sources,  
7 taking into account relevant lists of essential medicines established by European  
8 competent authorities, that could be used to mitigate the negative impacts of potential  
9 drug shortages
  - 10 ○ Criteria for evaluation of the suitability of production and quality control methods
  - 11 ○ Guidelines for the elaboration of monographs covering working methods, content and  
12 template
  - 13 ○ Guidelines for maintenance and vigilance of published monographs including criteria for  
14 revision/deletion and procedure for users/stakeholders/interested parties to raise  
15 potential issues.
- 16 • Selection, prioritisation, elaboration and revision of monographs describing standardised stock  
17 preparations of human medicines at risk of shortages according to the criteria and guidelines of  
18 the above-mentioned framework.
- 19 • In the event of active drug shortage, provide, if and when relevant, recommendations and guidance  
20 concerning pharmaceutical preparations that could be used to mitigate the negative impacts of  
21 the drug shortage.
- 22 • Establishment and maintenance of a respective Technical Guide and General Notices.

### 23 *Profile for experts\**

- 24 • Current expertise in development and production of pharmaceutical extemporaneous and stock  
25 preparations
- 26 • Current expertise in analytical procedures related to quality control of ingredients (APIs and  
27 excipients) and pharmaceutical preparations and in their development
- 28 • Access to preparation or laboratory facilities for verification of production methods and analytical  
29 procedures proposed for inclusion in monographs
- 30 • Several years of experience in one or more of the following fields:
  - 31 ○ Pharmaceutical development and/or manufacturing of extemporaneous and stock  
32 pharmaceutical preparations (in a community or hospital pharmacy, research unit, or in  
33 pharmaceutical industry)
  - 34 ○ Analytical procedure development and verification of medicinal preparations in a  
35 pharmaceutical manufacturing setting (including research and development), in a  
36 regulatory authority, in a community or hospital pharmacy or in an independent testing  
37 laboratory
  - 38 ○ Market surveillance of quality in a regulatory authority
  - 39 ○ Assessment of the relevant parts of applications for marketing authorisation of medicinal  
40 products (including safety assessment)
  - 41 ○ Elaboration/assessment of monographs for national or regional formularies

42 \*Observer(s) from the CD-P-PH are welcome to participate, especially during the establishment of  
43 the framework

## 1 **ENVSUS Working Party (Environmental Sustainability)**

### 2 *Terms of reference*

- 3 • Advise the Commission on the best possible approaches to addressing environmental sustainability
- 4 in the Ph. Eur.
- 5 • Identify the current state of affairs in relation to the activities already being undertaken today to
- 6 address environmental sustainability in the Ph. Eur.
- 7 • Scan the environment to identify relevant legislation and guidance impacting the Ph. Eur. in
- 8 the field of environmental sustainability as well as technological/scientific developments in
- 9 the field, monitor their developments and assess their impact on the Ph. Eur.
- 10 • Draft the Ph. Eur. strategy on 'environmental sustainability'.
- 11 • Co-operate with and consult other Ph. Eur. groups of experts and working parties, where relevant
- 12 and advise them on environmental sustainability principles/aspects to be incorporated in their
- 13 work.
- 14 • Cooperate with the OMCL working group on environmental sustainability.

### 15 *Profile for experts*

- 16 • People responsible for environmental sustainability in e.g. control laboratories (whether private or
- 17 public) or in the pharmaceutical or chemical industry or in academia.
- 18 • Representatives of relevant European agencies (such as the European Commission (e.g. DG
- 19 Research & Innovation), EEA, ECHA) with experience/knowledge in environmental sustainability\*
- 20 • Representative of the OMCL working group on environmental sustainability \*
- 21 (*\* ad hoc participation might be considered dependent on availability of those representatives*)

## 22 **EXP Working Party (Excipient performance)**

### 23 *Terms of reference*

- 24 • Drafting and maintaining the FRC (Functionality Related Characteristics) sections of monographs on
- 25 excipients to reflect current best practices, in consultation with the appropriate Groups of Experts
- 26 or Working Parties of the Ph. Eur.
- 27 • Review, where necessary, and maintenance of general chapter 5.15 FRCs of excipients to align it
- 28 with current regulatory guidance (e.g. ICH Q8 guideline)
- 29 • Drafting and maintenance of the text on co-processed excipients
- 30 • Review pharmacopoeial and other regulatory texts on general information on excipients with a
- 31 view to proposing necessary additions and updates, where relevant

### 32 *Profile for experts*

- 33 • Current expertise in analytical procedures (especially those included in the Ph. Eur. section 2.9.
- 34 Pharmaceutical technical procedures), related to control of excipients and in development of such
- 35 analytical procedures
- 36 • Several years of experience in one or more of the following fields:
  - 37 ○ Quality control of excipients in a bulk or pharmaceutical manufacturing setting
  - 38 ○ Pharmaceutical and excipient research and development
  - 39 ○ Assessment of the relevant parts of applications for marketing authorisation within a
  - 40 medicines agency
  - 41 ○ Development of analytical procedures for control of excipients, comprising those to
  - 42 determine excipient performance (FRCs) in a research and development environment
  - 43 ○ Pharmaceutical quality control in an independent testing laboratory

## 1 **EXS Working Party (Excipient Strategy)**

### 2 *Terms of reference*

- 3 • Identify and discuss best possible approach(es) to address the quality and the standard setting  
4 process of excipients for pharmaceutical use in the Ph. Eur. in view of making concrete  
5 recommendations to the Ph. Eur. Commission.

6 This would include, but is not limited to:

- 7 ○ the typical structure and content of an individual monograph on such an excipient
- 8 ○ the evaluation of the need for optional test(s) depending on the possible uses of the  
9 excipients (e.g. FRC section)
- 10 ○ the evaluation of the need for (a) specific technical guide(s)
- 11 ○ the review of terms of reference of groups of experts and working parties dealing with such  
12 excipients (including repartition of tasks between groups and ways of working between  
13 groups),
- 14 ○ The review of existing general monographs (such as Substances for pharmaceutical use  
15 (2034)) to appropriately cover such excipients
- 16 • Considering the recent example of *nitrites in excipients*, the specific challenges related to setting  
17 specifications for excipients in the Ph. Eur., the discussion around impurities (to cite some  
18 examples), propose appropriate control strategies for excipients and consequently, approaches for  
19 elaboration and revision of Ph. Eur. Monographs (general or individual ones) and/or general  
20 chapters for excipients for pharmaceutical use

### 21 *Profile for experts*

- 22 • Ideally a representative (e. g. Chairs) of each group dealing with excipients (esp. groups 9, 13H and  
23 CEL, CRB, EXP working party)
- 24 • Current expertise in pharmaceutical analytical procedures, related to quality control of excipients  
25 for pharmaceutical use and in development of such analytical procedures
- 26 • Several years of experience with excipients in one or more of the following fields:
  - 27 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
28 medicines agency
  - 29 ○ Market surveillance testing
  - 30 ○ Quality control or development of excipients for pharmaceutical use
  - 31 ○ Development and verification of analytical procedures

32 The EXS WP may preferably be chaired by a member of the Ph. Eur. Commission.

## 33 **GLS Working Party (Glass Containers)**

### 34 *Terms of reference*

- 35 • Drafting and revision of texts in the field of glass containers

### 36 *Profile for experts*

- 37 • Current expertise in the production of glass containers, analytical procedures, related to quality  
38 control of glass containers and in development of such analytical procedures
- 39 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
40 inclusion in general chapters
- 41 • Several years of experience in one or more of the following fields:
  - 42 ○ Quality control in a pharmaceutical manufacturing setting for control of glass containers
  - 43 ○ Production and/or quality control of glass containers in an industrial setting
  - 44 ○ Market surveillance of quality in a regulatory authority

- 1           ○ Pharmaceutical quality control in an independent testing laboratory
- 2           ○ Development of analytical procedures for control of glass containers in a research and
- 3           development environment

#### 4 **GTP Working Party (Gene Therapy Products)**

##### 5 *Terms of reference*

- 6           • Drafting and revision of texts in the field of gene therapy medicinal products
- 7           • Maintaining regular exchanges to ensure coordination of approaches with the CTP Working Party
- 8           in relevant areas

##### 9 *Profile for experts*

- 10          • Current expertise in analytical procedures related to development and quality control of gene
- 11          therapy products and in development of such analytical procedures
- 12          • Several years of experience in one or more of the following fields:
- 13           ○ Development of gene therapy products
- 14           ○ Quality control of gene therapy products in a pharmaceutical manufacturing setting or in a
- 15           hospital environment
- 16           ○ Assessment of applications for marketing authorisation of gene therapy products
- 17           ○ Marketing surveillance of quality in a regulatory authority
- 18           ○ Pharmaceutical quality control in an independent testing laboratory
- 19           ○ Development of analytical procedures for control of gene therapy products in a research
- 20           and development environment
- 21           ○

#### 22 **HMM Working Party (Homoeopathic Manufacturing Methods)**

##### 23 *Terms of reference*

- 24          • Drafting and revision of monographs in the field of homoeopathic manufacturing methods

##### 25 *Profile for experts*

- 26          • Knowledge of currently used homoeopathic manufacturing methods
- 27          • Several years of experience in one or more of the following fields:
- 28           ○ Assessment of application for marketing authorisation of homoeopathic products within a
- 29           medicines agency or equivalent
- 30          • Industry representatives are normally not appointed to the HMM Working Party. They may be
- 31          invited to contribute to elaboration of monographs during hearings organised on a case-by-case
- 32          basis by the Secretariat

#### 33 **HOM Working Party (Homoeopathic Raw Materials and Stocks)**

##### 34 *Terms of reference*

- 35          • Drafting and revision of texts in the field of homoeopathic raw materials and stocks

##### 36 *Profile for experts*

- 37          • Current expertise in pharmaceutical analytical procedures, related to quality control of
- 38          homoeopathic raw materials and stocks and in development of such analytical procedures
- 39          • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 40          inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical
- 41          procedures and drafting of texts
- 42          • Several years of experience in one or more of the following fields:

- 1           ○ Quality control of homoeopathic raw materials and stocks in a pharmaceutical
- 2           manufacturing setting
- 3           ○ Assessment of applications for marketing authorisation of homoeopathic products within
- 4           an agency
- 5           ○ Quality control of homoeopathic raw materials and stocks in an independent testing
- 6           laboratory
- 7           ○ Development of analytical procedures for control of homoeopathic raw materials and
- 8           stocks in a research and development environment
- 9           ○ Analytical procedure development, and verification in a regulatory authority

## 10 **HTS Working Party (High Throughput Sequencing for the detection of extraneous agents)**

### 11 *Terms of reference*

- 12           • Elaboration of general chapter 2.6.41 to describe High Throughput Sequencing (HTS) methods for
- 13           the detection of extraneous agents and provide guidelines for their validation
- 14           • To advise the Commission and Groups of Experts on the need to revise other Ph. Eur. texts, further
- 15           to the elaboration of general chapter 2.6.41 and provide support to Group of Experts requiring
- 16           the inclusion of HTS methods for extraneous agent detection in their texts

### 17 *Profile for experts*

- 18           • Current expertise in HTS **for the detection of extraneous agents** in biologicals, and in
- 19           the development and validation of analytical procedures based on HTS
- 20           • Several years of experience in one or more of the following fields:
  - 21           ○ Use of HTS techniques for quality control of biological products in a pharmaceutical
  - 22           manufacturing setting, a regulatory authority or an independent testing laboratory
  - 23           ○ Development and validation of analytical procedures based on HTS for the detection of
  - 24           extraneous agents, in a research and development environment
  - 25           ○ Assessment of the relevant parts of applications for marketing authorisation within a
  - 26           medicines agency

## 27 **INH Working Party (Inhalations)**

### 28 *Terms of reference*

- 29           • Drafting and revision of monographs and general chapters in the field of preparations for inhalation
- 30           and nasal sprays or powders.
- 31           • International harmonisation of related general chapters

### 32 *Profile for experts*

- 33           • Current expertise in pharmaceutical analytical procedures, related to quality control of
- 34           preparations for inhalation and nasal sprays or powders and in development of such analytical
- 35           procedures
- 36           • Several years of experience in one or more of the following fields related to preparations for
- 37           inhalation and nasal sprays or powders:
  - 38           ○ Quality control in a pharmaceutical manufacturing setting
  - 39           ○ Market surveillance of quality in a regulatory authority
  - 40           ○ Assessment of applications for marketing authorisation within a medicines agency
  - 41           ○ Development of analytical procedures for control of such preparations in a research and
  - 42           development environment
  - 43           ○ Pharmaceutical quality control in an independent testing laboratory
  - 44           ○ Analytical procedure development and verification in a regulatory authority

1 **MAB Working Party (Monoclonal Antibodies)**

2 *Terms of reference:*

- 3 • To undertake a pilot phase to elaborate general methods for analysis of monoclonal antibodies and  
4 individual monographs using the multisource approach (according to document PA/PH/Exp. MAB/T  
5 (14) 1)
- 6 • Drafting and revision of texts in the field of monoclonal antibodies

7 *Profile for experts*

- 8 • Current expertise in pharmaceutical analytical procedures, related to quality control of monoclonal  
9 antibodies and in development of such analytical procedures
- 10 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
11 inclusion in monographs or access to licensing files. **Essential:** Active involvement in laboratory  
12 verification of analytical procedures and drafting of texts
- 13 • Several years of experience in one or more of the following fields:
- 14 ○ Quality control of monoclonal antibodies in a pharmaceutical manufacturing setting
- 15 ○ Market surveillance of quality in a regulatory authority
- 16 ○ Assessment of applications for marketing authorisation of monoclonal antibodies within an  
17 agency
- 18 ○ Development of analytical procedures for control of monoclonal antibodies in a research  
19 and development environment
- 20 ○ Pharmaceutical quality control in an independent testing laboratory

21 **MG Working Party (General methods)**

22 *Terms of reference*

- 23 • Drafting and revision of general chapters, particularly in the field of chemical and physico-chemical  
24 analysis.
- 25 • If needed, requests the nomination of ad hoc specialists to create sub-groups for specific general  
26 chapters on the work programme, and management of the activities for the elaboration or revision  
27 of these general chapters within the sub-groups.
- 28 • Co-operation with other groups of experts and working parties which are in charge of elaboration  
29 and revision of general chapters where relevant.
- 30 • Maintenance of template for general methods

31 *Profile for experts*

- 32 • Members of a regulatory authority, universities or the pharmaceutical/chemical industries
- 33 • Current expertise and extensive knowledge in pharmacopoeial procedures and/or instruments  
34 used in the quality control of active substances, excipients and/or medicinal products and in  
35 development of analytical procedures
- 36 • Several years of experience in one or more of the following fields:
- 37 ○ Analytical procedure development and verification in e.g. analytical or pharmaceutical  
38 development, a regulatory authority, or testing laboratory
- 39 ○ Quality control of active substances, excipients and/or medicinal products
- 40 ○ Market surveillance of quality of medicinal products in a regulatory authority
- 41 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
42 medicines agency

## 1 **mRNAVAC Working Party (mRNA Vaccines for human use)**

### 2 *Terms of reference*

- 3 • Drafting and revision of texts in the field of mRNA vaccines for human use

### 4 *Profile for experts*

- 5 • Current expertise in analytical procedures related to the quality control of mRNA vaccines for  
6 human use, their components and their formulation
- 7 • Significant experience in one or more of the following fields:
  - 8 ○ Quality control of mRNA vaccines for human use and their components in a pharmaceutical  
9 manufacturing setting
  - 10 ○ Quality control/batch release/market surveillance of mRNA vaccines for human use and  
11 their components in an independent testing laboratory (e.g. OMCL)
  - 12 ○ Pharmaceutical development related to the formulation of mRNA vaccines for human use
  - 13 ○ Analytical development related to mRNA vaccines for human use and their components
  - 14 ○ Assessment of the relevant parts of applications for marketing authorisation within a  
15 medicines agency

## 16 **MYC Working Party (Mycoplasma)**

### 17 *Terms of reference*

- 18 • Revision of general chapter 2.6.7 *Mycoplasmas* in order to update it with the current practices in  
19 the field of mycoplasma testing

### 20 *Profile for experts*

- 21 • Current expertise in mycoplasma testing of medicinal products and in development of analytical  
22 procedures
- 23 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
24 inclusion in monographs,
- 25 • Several years of experience in one or more of the following fields:
  - 26 ○ Mycoplasma testing in a pharmaceutical manufacturing setting
  - 27 ○ Mycoplasma testing in an official control laboratory for medicines
  - 28 ○ Mycoplasma testing in an independent testing laboratory
  - 29 ○ Development of analytical procedures for mycoplasmas in a research and development  
30 environment

## 31 **NANO Working Party (Nanomedicines)**

### 32 *Terms of reference*

- 33 • Drafting and revision of texts in the field of nanomedicines (e.g. nanoparticle dispersions, like for  
34 example iron sucrose concentrated solution, liposomal formulations, and related analytical  
35 procedures)
- 36 • Provision of expertise in the field of nanomedicines to other groups where relevant

### 37 *Profile for experts*

- 38 • Current expertise in the development and/or quality control of nanomedicines and in development  
39 of relevant analytical procedures
- 40 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
41 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
42 procedures and drafting of texts
- 43 • Several years of relevant experience in one or more of the following fields:

- 1 ○ Quality control in a pharmaceutical manufacturing setting or in an independent testing
- 2 laboratory (e.g. Market surveillance of quality in a regulatory authority) related to
- 3 respective formulations
- 4 ○ Pharmaceutical development related to respective formulations
- 5 ○ Development of analytical procedures related to respective formulations
- 6 ○ Assessment of the relevant parts of applications for marketing authorisation within
- 7 a medicines agency

#### 8 **P4BIO Working Party (P4 Bio)**

##### 9 *Terms of reference*

- 10 • Drafting and revision of monographs in the field of single-source biologicals

##### 11 *Profile for experts*

- 12 • Group P4Bio is restricted to regulators from Ph. Eur. Member states however industry
- 13 representatives may be invited to contribute by submission of data and interaction with the group
- 14 via the Secretariat
- 15 • Current expertise in pharmaceutical analytical procedures, related to quality control of biologicals
- 16 and in development of such analytical procedures
- 17 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 18 inclusion in monographs or access to licensing files (essentially originating from CAP), **Essential:**
- 19 Active involvement in laboratory verification of analytical procedures and drafting of texts and
- 20 • Several years of experience in one or more of the following fields:
  - 21 ○ Quality control in a regulatory authority
  - 22 ○ Assessment of the relevant parts (biologicals) of applications for marketing authorisation
  - 23 ○ Market surveillance of quality in a regulatory authority

#### 24 **PaedF Working Party (European Paediatric Formulary)**

##### 25 *Terms of reference*

- 26 • Elaboration, and revision of monographs on paediatric preparations according to criteria and
- 27 guidelines approved by the CD-P-PH
- 28 • Establishment and maintenance of a Technical Guide for the elaboration and maintenance of
- 29 monographs on paediatric preparations

##### 30 *Profile for experts*

- 31 • Current expertise in development and production of paediatric preparations (including
- 32 toxicologists)
- 33 • Current expertise in analytical procedures related to quality control of ingredients (APIs and
- 34 excipients) and preparations and in the development of such preparations and analytical
- 35 procedures; Access to laboratory facilities for verification of production methods and analytical
- 36 procedures proposed for inclusion in monographs
- 37 • Current expertise in clinical/pharmacological treatment of several paediatric age groups
- 38 • Several years of experience in one or more of the following fields:
  - 39 ○ Pharmaceutical development and/or manufacturing of paediatric preparations (in a
  - 40 community or hospital pharmacy, research unit, or in pharmaceutical industry)
  - 41 ○ Analytical procedure development and verification of medicinal preparations in a
  - 42 pharmaceutical manufacturing setting (including research and development), in a
  - 43 regulatory authority, in a community or hospital pharmacy or in an independent testing
  - 44 laboratory
  - 45 ○ Market surveillance of quality in a regulatory authority

- 1 ○ Assessment of the relevant parts of applications for marketing authorisation of paediatric
- 2 medicinal products (including safety assessment)
- 3 ○ Elaboration/assessment of monographs for national (paediatric) formularies
- 4 ○ Clinical/pharmacological treatment of children belonging to several age groups

#### 5 **PAT Working Party (Process Analytical Technology)**

##### 6 *Terms of reference*

- 7 ● Review and revision of existing general monographs and chapters in view of needs arising from
- 8 Process Analytical Technology (PAT), Continuous Manufacturing (CM), Real Time release testing
- 9 (RTRT) or Quality by Design (QbD) concepts
- 10 ● Identify and discuss the implication of the above mentioned concepts on the texts of European
- 11 Pharmacopoeia and make proposals to the Commission where needed
- 12 ● Support and advise other group of experts and working parties where elements of the above
- 13 mentioned concepts are concerned.

##### 14 *Profile for experts*

- 15 ● Expertise in chemical or pharmaceutical development and analytical procedures applied during
- 16 manufacture and to active substances or finished pharmaceutical preparations
- 17 ● Several years of experience in one or more of the following fields
- 18 ○ Development of pharmaceutical preparations using PAT, CM, RTRT or QbD concepts in an
- 19 industrial setting
- 20 ○ Assessment of the relevant parts of applications for marketing authorisation containing
- 21 PAT, CM, RTRT or QbD concepts within a medicines agency
- 22 ○ Development of control strategies including PAT, CM, RTRT or QbD concepts approaches
- 23 for testing of active substances or pharmaceutical preparations
- 24 ○ Development of pharmaceutical preparations using modelling and chemometrics
- 25 associated with the analytical aspects for PAT

#### 26 **POW Working Party (Powder Characterisation)**

##### 27 *Terms of reference*

- 28 ● Drafting and revision of general chapters in the field of powder characterisation techniques
- 29 ● International harmonisation of general chapters

##### 30 *Profile for experts*

- 31 ● Current expertise in analytical procedures for powder characterisation, related to quality control of
- 32 active substances and excipients and in development of such analytical procedures
- 33 ● Several years of experience in one or more of the following fields:
- 34 ○ Quality control of active substances and excipients in a pharmaceutical manufacturing
- 35 setting
- 36 ○ Assessment of the relevant parts of applications for marketing authorisation
- 37 ○ Market surveillance of quality in a regulatory authority
- 38 ○ Development of analytical procedures for characterisation of powders in a research and
- 39 development environment
- 40 ○ Pharmaceutical quality control in an independent testing laboratory

#### 41 **PRP Working Party (Precursors for Radiopharmaceutical Preparations)**

##### 42 *Terms of reference*

- 43 ● Drafting and revision of texts in the field of non-radioactive precursors for radiopharmaceutical
- 44 preparations

1 *Profile for experts*

- 2 • Expertise in chemical, pharmaceutical and radiopharmaceutical analytical procedures, related to  
3 quality control of radiopharmaceutical preparations and their precursors
- 4 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
5 inclusion in monographs. **Essential:** Active involvement in laboratory verification of analytical  
6 procedures and drafting of texts
- 7 • Several years of experience in one or more of the following fields:
- 8 ○ Quality control of radiopharmaceutical preparations and their precursors
- 9 ○ Quality control of synthetic organic and/or inorganic products in a chemical or  
10 pharmaceutical setting
- 11 ○ Quality control in an independent testing laboratory
- 12 ○ Development of analytical procedures for the control of radiopharmaceutical preparations  
13 and their precursors

14 **PST Working Party (Pesticide Residues)**

15 *Terms of reference*

- 16 • Drafting and revision of texts in the field of pesticide residues

17 *Profile for experts*

- 18 • Current expertise in pesticide analysis, related to quality control of active substances and excipients  
19 and in development of such analytical procedures
- 20 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
21 inclusion in monographs
- 22 • Several years of experience in one or more of the following fields:
- 23 ○ Quality control for pesticide residues in herbals in a pharmaceutical or bulk manufacturing  
24 setting
- 25 ○ Market surveillance of quality in a regulatory authority
- 26 ○ Pharmaceutical quality control in an independent testing laboratory
- 27 ○ Development of analytical procedures for pesticide residues in a research and development  
28 environment

29 **ROP Working Party (Rules of Procedure)**

30 *Terms of reference*

- 31 • Elaborating any document or updating existing ones (Rules of Procedure, Guide for work of  
32 the European Pharmacopoeia, Code of Practice) in line with the decisions taken by the Commission.
- 33 • Supporting the implementation of the revised documents (e.g. in form of PowerPoint  
34 presentations, webinars or any other mean deemed appropriate by the ROP WP members to  
35 ensure consistent and appropriate dissemination of the information provided and changes made  
36 as well as their application)

37 *Profile for experts*

- 38 • Members of national pharmacopoeia authorities of a Ph. Eur. Member state or delegations to  
39 the Commission.

40 The ROP WP is chaired by the Chair of the Ph. Eur. Commission.

41 **SDA Working Party (Spectroscopy and Data Analysis)**

42 *Terms of reference*

- 43 • Drafting and revision of general chapters in the fields of:

- 1           ○ Measurement techniques relying on spectroscopy, with the exception of specific
- 2           spectroscopic techniques where the drafting and revision of general chapters is allocated to
- 3           other, more specialised groups of experts and working parties.
- 4           ○ Chemical imaging techniques, e.g. spectral and multispectral imaging, electron microscopy,
- 5           field effect and atomic force microscopies, optical and X-ray tomography, etc.
- 6           ○ Chemometrics and data sciences techniques relying on multivariate data analysis, numerical
- 7           methods, algorithmics, data modelling, data mining, artificial intelligence, etc., and image
- 8           analysis techniques.
- 9           ● to support and advise other group of experts and working parties where elements of the above
- 10          mentioned measurement and data analysis techniques are concerned and where relevant.

#### 11 *Profile for experts*

- 12          ● Current expertise in spectroscopy related to quality control of active substances, excipients or
- 13          medicinal products, in development of analytical procedures.
- 14          ● Ideally, access to laboratory facilities for verification and validation of analytical procedures
- 15          proposed for inclusion in general chapters and monographs
- 16          ● Several years of experience in one or more of the following fields:
  - 17               ○ Use of spectroscopic techniques for pharmaceutical quality control in a pharmaceutical
  - 18               manufacturing setting, a regulatory authority or an independent testing laboratory.
  - 19               ○ Development of pharmaceutical in-, on-, or at-line analytical procedures using spectroscopic
  - 20               or imaging techniques or chemometrics and data analysis, in a research and development
  - 21               environment.
  - 22               ○ Assessment of applications for marketing authorisation.
  - 23               ○ Use of spectroscopic techniques for the market surveillance of the quality of pharmaceutical
  - 24               substances or medicinal products.

#### 25 **SIT Working Party (Second identification test)**

##### 26 *Terms of reference*

- 27          ● To support and advise the Commission, Groups of Experts or Working Parties on
- 28          revision/suppression of existing identification series, notably arising from the REACH regulation,
- 29          where relevant.
- 30          Propose to the Commission further items for the work programme (such as monographs with
- 31          missing second identification or the replacement of identification tests not in line with
- 32          the instrumentation available in pharmacies)

##### 33 *Profile for experts*

- 34          ● Pharmacists regularly involved in preparation of extemporaneous or stock preparation of medicinal
- 35          products in community pharmacies or hospitals as well as in the analysis of the pharmaceutical
- 36          substances used
- 37          ● Pharmacists or chemists with special interest/expertise in analytical techniques commonly
- 38          available in pharmacies
- 39          ● Members of a regulatory authority
- 40          ● Access to laboratory facilities for verification of analytical procedures proposed for inclusion in
- 41          monographs

#### 42 **ST Working Party (Standard Terms)**

##### 43 *Terms of reference*

- 44          ● Development of standard terms and definitions for the Standard Terms database for dosage forms,
- 45          units of presentation, routes of administration, packaging and related terms at the request of
- 46          Competent authorities of Member States and certain non-member states (e.g. competent authority
- 47          members of ICH), the European Commission or the EMA.

1 *Profile for experts*

- 2 • Current expertise in pharmaceutical dosage forms
- 3 • Several years of experience in one or more of the following fields:
- 4 ○ Assessment of the pharmaceutical development part of applications for authorisation of
- 5 medicinal products
- 6 ○ Development of general monographs for dosage forms (group of experts or national
- 7 pharmacopoeia secretariat)
- 8 ○ Experience in formulation of medicinal products
- 9 • Members of the working party may be from a regulatory authority or universities

10 **SUT Working Party (Sutures)**

11 *Terms of reference*

- 12 • Drafting and revision of texts in the field of sutures

13 *Profile for experts*

- 14 • Expertise in pharmaceutical analytical procedures, related to quality control of sutures and in
- 15 development of such analytical procedures
- 16 • Several years of experience in one or more of the following fields:
- 17 ○ Quality control of sutures
- 18 ○ Development of analytical procedures for control of sutures

19 **TCM Working Party (Traditional Chinese Medicines)**

20 *Terms of reference*

- 21 • Drafting and revision of texts in the field of herbal drugs and herbal drug preparations preferably
- 22 based on the principle of adapting/improving existing monographs or analytical procedures to
- 23 control herbal drugs used in Traditional Chinese Medicines (TCM)
- 24 • Drafting general chapters related to the specific needs of TCM herbal drugs

25 *Profile for experts*

- 26 • Current expertise in pharmaceutical analytical procedures, related to quality control of herbal drugs
- 27 and herbal drug preparations and in development of such analytical procedures
- 28 • Access to laboratory facilities for verification and validation of analytical procedures proposed for
- 29 inclusion in monographs
- 30 • Several years of experience in one or more of the following fields:
- 31 ○ Quality control of herbal drugs/herbal drug preparations in a manufacturing setting
- 32 ○ Pharmaceutical quality control of herbal drugs and herbal drug preparations in an
- 33 independent testing laboratory
- 34 ○ Development and validation of analytical procedures for control of herbal drugs
- 35 ○ Involvement in market surveillance or regulatory oversight of imported TCM herbal drugs
- 36 • **Essential:** Active involvement in laboratory verification of analytical procedures for TCM herbal
- 37 drugs and in drafting of texts.
- 38 • Development and validation of analytical procedures for identification and/or quantification of
- 39 herbal drug constituents based on chromatographic separation techniques (HPLC, GC, HPTLC)
- 40 • Knowledge in cultivation, harvesting, processing and use of TCM herbal drugs

**1 VIT Working Party (Vitamins)****2 Terms of reference**

- 3 • Drafting and revision of monographs in the field of vitamins and vitamin derivatives

**4 Profile for experts**

- 5 • Current expertise in pharmaceutical analytical procedures, related to quality control of vitamins  
6 and excipients and in development of such analytical procedures. *The need of a specialist for*  
7 *vitamin D type substances is highlighted*
- 8 • Access to laboratory facilities for verification and validation of analytical procedures proposed for  
9 inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical  
10 procedures and drafting of texts.
- 11 • Several years of experience in one or more of the following fields:
  - 12 ○ Quality control of vitamins in a pharmaceutical or bulk manufacturing setting
  - 13 ○ Market surveillance of quality in an official control laboratory for medicines
  - 14 ○ Pharmaceutical quality control in an independent testing laboratory
  - 15 ○ Development of analytical procedures for control of vitamins in a research and  
16 development environment
  - 17 ○ Analytical procedure development and verification in a national pharmacopoeia laboratory

**18 WAT Working Party (Water)****19 Terms of reference**

- 20 • Drafting and revision of texts in the field of water
- 21 • International harmonisation of relevant texts

**22 Profile for experts**

- 23 • Current expertise in analytical procedures applicable to water analysis and in development of such  
24 analytical procedures
- 25 • Several years of experience in one or more of the following fields:
  - 26 ○ Quality control of water in a pharmaceutical manufacturing setting
  - 27 ○ Inspection of manufacturing sites
  - 28 ○ Pharmaceutical quality control in an independent testing laboratory
  - 29 ○ Development of analytical procedures for control of pharmaceutical waters in a research  
30 and development environment

31

**TERMS OF REFERENCE AND PROFILE FOR MEMBERS OF  
"DORMANT" WORKING PARTIES:**

Once a working party has finalised its work programme i.e. the text(s) elaborated or revised by the working party has(have) been adopted by the Commission, the mandate of the working party can be extended as the support and advice of Pharmacopoeia members may still be needed e.g. by other Ph. Eur. groups or by the Secretariat to answer to questions users may rise when implementing the texts for example. The task of this working party will mainly consist in answering to enquiries, questions sent via the Secretariat i.e. by correspondence. The terms of reference of these working parties are described accordingly.

**GEL Working Party (Gelatin)**

*Terms of reference*

- To provide support and advice in case of questions raised by e.g. users in the field of gelatin

*Profile for experts:*

- Current expertise in pharmaceutical analytical procedures, related to quality control of gelatin and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
  - Quality control in a pharmaceutical or bulk manufacturing setting (gelatin or use of gelatin)
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Analytical procedure development and verification in a regulatory authority
  - Development of pharmaceutical analytical procedures using near infrared spectroscopy for gelatin identification

**LEC Working Party (Lecithins)**

*Terms of reference*

- To provide support and advice in case of questions raised by e.g. users in the field of lecithins

*Profile for experts*

- Current expertise in pharmaceutical analytical procedures, related to quality control of lecithins and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential:** Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
  - Quality control of lecithins in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of analytical procedures for control of lecithins in a research and development environment
  - Analytical procedure development and verification in a regulatory authority