

TERMS OF REFERENCE AND PROFILE FOR MEMBERS OF GROUPS OF EXPERTS AND WORKING PARTIES

The terms of reference and profiles shown below have been approved by the Ph. Eur. Commission at its 163rd session (March 2019). Experts shall fulfil the profile described. It is also expected that experts once appointed by the Ph. Eur. Commission will be available to attend meetings and are prepared to draft and/or verify monographs and general chapters and when required in the profile, have access to a laboratory for experimental verifications.

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

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

Pro memoria:

- *Candidates from Ph. Eur. member states:* Applications are to be submitted to [your national pharmacopoeia authority \(NPA\)](#).
- *Candidates from non Ph. Eur. member states:* Applications are to be submitted to the EDQM via the [Helpdesk](#) (please consult the following webpage <https://www.edqm.eu/en/join-network> for more information)

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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 attributes in
- 5 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 the
- 11 EDQM website.

12

13 *Profile for experts*

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

22 *Profile for ad-hoc specialists on alternative microbiological methods (please indicate this field of expertise on*

23 *the nomination form, if applicable)*

- 24 • Current expertise in microbiological analytical methods, related to quality control of active substances,
- 25 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 setting,
- 28 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 development
- 33 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, synthetic
- 37 peptides including glycan mapping
- 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, peptides
- 41 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 42 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 43 texts
- 44 • Several years of experience in one or more of the following fields:

- 1 ○ Quality control of biological products, biotechnological products, peptides in a pharmaceutical
- 2 manufacturing setting
- 3 ○ Quality control in a regulatory authority
- 4 ○ Quality control of biological or biotechnological products in an independent testing laboratory
- 5 ○ Development of methods for control of biological products, biotechnological products,
- 6 peptides in a research and development environment
- 7 ○ Method development and verification in a regulatory authority
- 8 ○ Assessment of the relevant parts of application for marketing authorisation of biological and
- 9 biotechnological products within a medicines agency

10 *Profile for glycan mapping ad-hoc specialists (please indicate this field of expertise on the nomination form, if*
 11 *applicable)*

- 12 • Current expertise in pharmaceutical analytical methods, related to quality control of glycoproteins and
- 13 in development of control methods
- 14 • Several years of experience in one or more of the following fields:
 - 15 ○ Quality control of glycoproteins in a pharmaceutical manufacturing setting
 - 16 ○ Market surveillance of quality of glycoproteins in a regulatory authority
 - 17 ○ Pharmaceutical quality control of glycoproteins in an independent testing laboratory
 - 18 ○ Assessment of the relevant parts of application for marketing authorisation of biological and
 - 19 biotechnological products within a medicines agency
 - 20 ○ Method development and verification in a regulatory authority
 - 21 ○ Development of control methods for glycoproteins in a research and development environment

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

23 *Terms of reference*

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

25 *Profile for experts*

- 26 • Current expertise in the field of blood products, notably related to quality control of and development of
- 27 control methods
- 28 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 29 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 30 texts
- 31 • Several years of experience in one or more of the following fields:
 - 32 ○ Quality control of blood products in a pharmaceutical or bulk manufacturing setting
 - 33 ○ Batch release or market surveillance of Human Blood, Plasma and Plasma Products in a
 - 34 regulatory authority
 - 35 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
 - 36 agency
 - 37 ○ Quality control of blood products in an independent testing laboratory
 - 38 ○ Method development and verification in a regulatory authority
 - 39 ○ Development of methods for control Human Plasma and Plasma Products in a research and
 - 40 development environment

41 **Group of Experts No. 7 (Antibiotics)**

42 *Terms of reference*

- 43 • Drafting and revision of texts in the field of antibiotic active substances
- 44 • Provision of expertise in the field of antibiotics to Group 17 where relevant

45 *Profile for experts*

- 46 • Current expertise in the fields of antibiotics

- 1 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 2 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 3 texts
- 4 • Several years of experience in one or more of the following fields:
- 5 ○ Quality control of antibiotics in a pharmaceutical manufacturing setting
- 6 ○ Quality control of antibiotics in a bulk manufacturing setting
- 7 ○ Quality control of antibiotics in a regulatory authority
- 8 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
- 9 agency
- 10 ○ Quality control of antibiotics in an independent testing laboratory
- 11 ○ Development of methods for control of antibiotics in a research and development environment
- 12 ○ Method development and verification in a regulatory authority

13 **Group of experts No. 9 (Inorganic Chemistry)**

14 *Terms of reference*

- 15 • Drafting and revision of monographs in the field of inorganic substances
- 16 • International harmonisation of monographs

17 *Profile for experts*

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

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

31 *Terms of reference*

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

33 *Profile for experts*

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

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

2 *Terms of reference*

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

5 *Profile for experts*

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

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

23 *Terms of reference*

- 24 • Drafting and revision of monographs in the field of natural, semi-synthetic and synthetic organic
25 substances
26 • Provision of expertise in the field of organic chemistry to the Group 17 where relevant

27 *Profile for experts*

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

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

43 *Terms of reference*

- 44 • Drafting and revision of dosage form monographs and pharmaceutical technical procedures
45 • Maintenance of dosage form related International Harmonisation topics such as:
46 ○ uniformity of dosage units
47 ○ dissolution

1 o disintegration

2 • Particulate contamination: visible and sub-visible particles

3 • Provision of expertise in the field of pharmaceutical technology to other groups where relevant

4 *Profile for experts*

5 • Current expertise in pharmaceutical development and control methods applied during manufacture and
6 to finished pharmaceutical preparations, in the relevant specialities defined in the terms of reference

7 • Several years of experience in one or more of the following fields:

8 o Development and quality control of pharmaceutical preparations in an industrial setting

9 o Assessment of the relevant parts of applications for marketing authorisation within a medicines
10 agency

11 o Development of methods for testing of pharmaceutical preparations in a research and
12 development environment

13 o Method development and verification in a regulatory authority

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

15 *Terms of reference*

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

17 *Profile for experts*

18 • Current expertise in pharmaceutical analytical methods, related to quality control of herbal drugs and
19 herbal drug preparations and in development of control methods

20 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
21 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
22 texts.

23 • Several years of experience in one or more of the following fields:

24 o Quality control of herbal drugs and herbal drug preparations in a pharmaceutical
25 manufacturing or bulk manufacturing setting

26 o Market surveillance of quality of herbals in a regulatory authority

27 o Assessment of the relevant parts of applications for marketing authorisation of herbal
28 medicinal products within a medicines agency

29 o Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent
30 testing laboratory

31 o Development of methods for control of herbal drugs in a research and development
32 environment

33 o Method development and verification in a regulatory authority

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

35 *Terms of reference*

36 • Drafting and revision of texts in the field of:

37 o surfactants

38 o fatty oils, fats and waxes

39 o fatty acids, fatty alcohols and their esters/ethers

40 o macrogols, macrogol derivatives and other polymers (i.e. carbomers)

41 o Paraffins

42 • International Harmonisation of the relevant monographs

43 *Profile for experts*

44 • Current expertise in pharmaceutical analytical methods, related to quality control in the relevant
45 specialities defined in the terms of reference

46 • Member of a regulatory authority , universities or the pharmaceutical/chemical industries

- 1 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
 2 monographs,
 3 **Essential:** Active involvement in laboratory verification of test methods and drafting of texts
 4 • Several years of experience in one or more of the following fields:
 5 ○ Quality control in a pharmaceutical manufacturing setting
 6 ○ Quality control of fats etc. in a bulk manufacturing setting
 7 ○ Market surveillance of quality in a regulatory authority
 8 ○ Pharmaceutical quality control of fats etc. in an independent testing laboratory
 9 ○ Development of methods for control of fats etc. in a research and development environment
 10 ○ Method development and verification in a regulatory authority

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

12 *Terms of reference*

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

14 *Profile for experts*

- 15 • Current expertise in pharmaceutical analytical methods, related to quality control of
 16 radiopharmaceutical preparations and in development of control methods
 17 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
 18 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
 19 texts
 20 • Several years of experience in one or more of the following fields:
 21 ○ Quality control of radiopharmaceutical preparations in a pharmaceutical manufacturing setting
 22 or in a hospital
 23 ○ Market surveillance of quality of radiopharmaceutical preparations in a regulatory authority
 24 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
 25 agency
 26 ○ Pharmaceutical quality control of radiopharmaceutical preparations in an independent testing
 27 laboratory
 28 ○ Method development and verification in a regulatory authority

29 **Group of Experts No. 15 (Human Vaccines and Sera)**

30 *Terms of reference*

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

33 *Profile for experts*

- 34 • Current expertise in analytical methods, related to quality control of vaccines and sera for human use
 35 and in development of control methods
 36 • Several years of experience in one or more of the following fields:
 37 ○ Quality control of vaccines and sera for human use in a pharmaceutical manufacturing setting
 38 ○ Batch release and market surveillance of quality of vaccines and sera for human use in a
 39 regulatory authority
 40 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
 41 agency
 42 ○ Quality control of vaccines and sera for human use in an independent testing laboratory

43 *Profile for botulinum toxins ad hoc specialists (please indicate this field of expertise on the nomination form, if 44 applicable)*

- 45 • Current expertise in analytical methods for botulinum toxins and in development of control methods
 46 • Several years of experience in one or more of the following fields:

- 1 ○ Quality control of botulinum toxins in a pharmaceutical manufacturing setting
- 2 ○ Batch release or market surveillance of quality of botulinum toxins in a regulatory authority
- 3 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
- 4 agency
- 5 ○ Pharmaceutical quality control of botulinum toxins in an independent testing laboratory
- 6 ○ Development of control methods for botulinum toxins in a research and development
- 7 environment

8 **Group of Experts No. 15V (Veterinary Vaccines and Sera)**

9 *Terms of reference*

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

11 *Profile for experts*

- 12 • Current expertise in suitable standards for IVMP, in methods related to quality control of these products
- 13 and in development of control methods
- 14 • Several years of experience in one or more of the following fields:
 - 15 ○ Quality control of IVMP in a regulatory authority
 - 16 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
 - 17 agency
 - 18 ○ Batch release and market surveillance of quality in a regulatory authority
 - 19 ○ Development of methods for control of IVMP in a research and development environment
- 20 • Industry representatives are normally not appointed to Group of Experts No. 15V. They may be invited
- 21 to contribute to elaboration of texts during hearings organised on a case-by-case basis by the
- 22 Secretariat.

23

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

25 *Terms of reference*

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

27 *Profile for experts*

- 28 • Current expertise in the fields covered by the terms of reference
- 29 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 30 texts, **Essential:** Active involvement in laboratory verification of test methods and drafting of texts
- 31 • Several years of experience in one or more of the following fields:
 - 32 ○ Quality control of plastic materials, plastic containers and closures in a pharmaceutical
 - 33 manufacturing setting
 - 34 ○ Quality control of plastic materials, plastic containers and closures in a regulatory authority
 - 35 ○ Quality control of plastic materials, plastic containers and closures in an independent testing
 - 36 laboratory
 - 37 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
 - 38 agency
 - 39 ○ Method development and verification in a regulatory authority

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

41 *Terms of reference*

- 42 • Drafting and revision of monographs on medicinal products containing chemically defined active
- 43 substances
- 44 • Drafting of monographs on active substances contained in these medicinal products if the monographs
- 45 are being elaborated in parallel and if deemed appropriate;
- 46 • Drafting and maintenance of the technical guide for the elaboration of monographs on medicinal
- 47 products containing chemically defined active substances

- 1 • Provision of expertise to other groups (such as Group P4) where relevant

2 *Profile for experts*

- 3 • Current expertise in pharmaceutical analytical methods, related to quality control of medicinal products
4 containing chemically defined active substances and in development of such methods
- 5 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
6 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
7 texts.
- 8 • Several years of experience in one or more of the following fields:
- 9 ○ Development and verification of test methods
- 10 ○ Quality control or development of medicinal products containing chemically defined active
11 substances
- 12 ○ Market surveillance testing
- 13 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
14 agency

15 **Group of Experts P4**

16 *Terms of reference*

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

19 *Profile for experts*

- 20 • Current expertise in pharmaceutical analytical methods, related to quality control of active substances,
21 excipients and medicinal products (with chemically defined active substances), and in development of
22 control methods
- 23 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
24 monographs or access to licensing files, **Essential:** Active involvement in laboratory verification of test
25 methods and drafting of texts.
- 26 • Several years of experience in one or more of the following fields:
- 27 ○ Assessment of the relevant parts of applications for marketing authorisation
- 28 ○ Market surveillance studies in a regulatory authority
- 29 ○ Method development and verification in a regulatory authority
- 30 • Group P4 is restricted to regulators from Ph. Eur. Member states however industry representatives may
31 be invited to contribute by submission of data and interaction with the group via the Secretariat

32 **ALG Working Party (Allergens)**

33 *Objective*

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

35 *Profile for experts*

- 36 • Current expertise in pharmaceutical analytical methods, related to quality control of allergens and in
37 development of control methods
- 38 • Several years of experience in one or more of the following fields:
- 39 ○ Quality control of allergen products in a pharmaceutical manufacturing setting
- 40 ○ Market surveillance of quality of allergen products in a regulatory authority
- 41 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
42 agency
- 43 ○ Pharmaceutical quality control of allergen products in an independent testing laboratory
- 44 ○ Development of methods for control of allergens in a research and development environment

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

2 *Terms of reference*

- 3
- 4 • Drafting and revision of general chapters in the field of bacterial endotoxins
 - 5 • Advising the Commission and expert groups on appropriate methods for the detection of bacterial endotoxins or pyrogens in substances for pharmaceutical use or pharmaceutical preparations.
 - 6 • Drafting and revision of general chapters in the field of the monocyte activation tests (MAT)
 - 7 • International Harmonisation of the relevant texts

8 *Profile for experts*

- 9
- 10 • Several years of experience in one or more of the following fields:
 - 11 ○ Quality control of parenteral preparations, active substances and/or excipients in a pharmaceutical manufacturing setting
 - 12 ○ Market surveillance of quality in a regulatory authority
 - 13 ○ Pharmaceutical quality control in an independent testing laboratory
 - 14 ○ Development of control methods for bacterial endotoxin test in a research and development environment
 - 15 ○ Access to laboratory facilities for verification and validation of methods proposed
- 16
- 17

18 *Profile for MAT ad hoc specialists (please indicate this field of expertise on the nomination form, if applicable)*

- 19
- 20 • Current expertise in practical application of the monocyte activation test
 - 21 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in monographs,
 - 22 • Several years of experience in one or more of the following fields:
 - 23 ○ Quality control of parenteral preparations, active substances and/or excipients in a pharmaceutical manufacturing setting
 - 24 ○ Market surveillance of quality in a regulatory authority
 - 25 ○ Pharmaceutical quality control in an independent testing laboratory
 - 26 ○ Development of control methods for monocyte activation test in a research and development environment
 - 27 ○ Method development and verification in a regulatory authority
- 28
- 29

30 **BSR Working Party (Bovine serum)**

31 *Terms of reference*

- 32
- 33 • Maintenance of the monograph *Bovine serum* (2262)
 - 34 • Drafting and revision of other texts pertaining to bovine sera as appropriate

35 *Profile for experts*

- 36
- 37 • Current expertise in analytical methods related to quality control of bovine sera and in development of control methods
 - 38 • Several years of experience in one or more of the following fields:
 - 39 ○ Quality control of bovine serum in a pharmaceutical manufacturing setting
 - 40 ○ Market surveillance of quality in a regulatory authority
 - 41 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
 - 42 ○ Pharmaceutical quality control in an independent testing laboratory
 - 43 ○ Development of methods for control of bovine serum in a research and development environment
- 44

1 **CE Working Party (Capillary Electrophoresis)**

2 *Terms of reference*

- 3 • Revision of the chapter 2.2.47 *Capillary electrophoresis*
- 4 • Advising the Commission on questions related to capillary electrophoresis in monographs drafted by
5 other groups of experts and working parties
- 6 • International Harmonisation of the relevant texts

7

8 *Profile for experts*

- 9 • Current expertise in *Capillary electrophoresis* techniques
- 10 • Several years of experience in the following fields:
 - 11 ○ Quality control of active substances, excipients and medicinal products, using capillary
12 electrophoresis techniques, in a pharmaceutical manufacturing setting, in a regulatory authority
13 or in any other testing laboratory
 - 14 ○ Development of capillary electrophoresis methods for control of active substances, excipients
15 and medicinal products in a research and development environment or at university
 - 16 ○ Access to laboratory facilities for verification and validation of methods proposed for inclusion
17 in monographs **Essential**: Active involvement in laboratory verification of test methods and
18 drafting of texts

19 **CEL Working Party (Cellulose)**

20 *Terms of reference*

- 21 • Drafting and revision of monographs on cellulose and cellulose derivatives
- 22 • International harmonisation of monographs on cellulose and cellulose derivatives

23 *Profile for experts*

- 24 • Current expertise in analytical methods for cellulose and cellulose derivatives and in development of
25 control methods
- 26 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
27 monographs, **Essential**: Active involvement in laboratory verification of test methods and drafting of
28 texts.
- 29 • Several years of experience in one or more of the following fields:
 - 30 ○ Quality control of cellulose and cellulose derivatives in a pharmaceutical or other industrial
31 manufacturing setting
 - 32 ○ Market surveillance of quality of cellulose and cellulose derivatives in a regulatory authority
 - 33 ○ Quality control of cellulose and cellulose derivatives in a regulatory authority
 - 34 ○ Development of control methods for cellulose and cellulose derivatives in a research and
35 development environment
 - 36 ○ Method development and verification in a regulatory authority

37 **CND Working Party (Conductivity)**

38 *Terms of reference*

- 39 • International harmonisation of general chapter 2.2.38 *Conductivity*

40 *Profile for experts*

- 41 • Current expertise in conductivity measurement
- 42 • Several years of experience in one or more of the following fields:
 - 43 ○ Quality control using conductivity measurement in a pharmaceutical manufacturing setting
 - 44 ○ Market surveillance of quality using conductivity measurement in a regulatory authority
 - 45 ○ Conductivity measurement for pharmaceutical analysis in an independent testing laboratory
 - 46 ○ Conductivity measurement in a regulatory authority

- 1 ○ Development of methods for conductivity measurement in a research and development
2 environment

3 **COL Working Party (Colour determination)**

4 *Terms of reference*

- 5 • Drafting and revision of monographs and texts in the field of instrumental determination of colour
6 (PDG item Q-07)
- 7 • Establishing correlation between measurement using Ph. Eur. Chapter 2.2.2 and the tristimulus type
8 instruments

9 *Profile for experts*

10 Several years of experience in one or more of the following fields:

- 11 ○ Users: Expertise in the use of tristimulus-type of colour measuring instruments in the field of
12 pharmaceutical development, quality control of pharmaceuticals, food, cosmetics or drinking
13 water
- 14 ○ Instrument suppliers: Personnel involved in user-support for practical application of
15 tristimulus-type instruments in the field of pharmaceutical development , quality control of
16 pharmaceuticals, food, cosmetics or drinking water
- 17 ○ Experience in research or university teaching related to instrumental colour determination of
18 liquids

19 **CRB Working Party (Carbohydrates)**

20 *Terms of reference*

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

23 *Profile for experts*

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

36 **CST Working Party (Chromatographic separation techniques)**

37 *Terms of reference*

- 38 • Revision of the chapter 2.2.46 *Chromatographic separation techniques*
- 39 • Revision of other chapters on chromatographic separation (e.g. 2.2.29, 2.2.30)
- 40 • International harmonisation of chapter 2.2.46 (PDG item G-20)
- 41 • Advising the Commission on questions related to chromatographic separation techniques in
42 monographs drafted by other groups of experts and working parties
- 43 • Co-operation with other groups of experts and working parties which use chromatographic separation
44 techniques where relevant

1 *Profile for experts*

- 2 • Current expertise in chromatographic separation techniques
- 3 • Several years of experience in one or more of the following fields:
 - 4 ○ Chromatographic quality control of active substances and/or excipients in a pharmaceutical
 - 5 manufacturing setting
 - 6 ○ Development of chromatographic methods for control of active substances, excipients and
 - 7 medicinal products in a research and development environment
 - 8 ○ Market surveillance of quality in a regulatory authority
 - 9 ○ Pharmaceutical quality control in an independent testing laboratory

10 **CTP Working Party (Cell Therapy Products)**11 *Terms of reference*

- 12 • Revision of general chapter 2.7.29 *Nucleated cell count and viability* in order to update it with new
- 13 automated technologies for cell enumeration (e.g. image cytometry)
- 14 • Revision of Ph. Eur. texts (monographs or chapters) where it might be necessary to account for chapter
- 15 5.2.12 *Raw materials of biological origin for the production of cell-based and gene therapy medicinal*
- 16 *products*
- 17 • Evaluation of the need to revise the introductory statement of the monograph on parenteral preparations
- 18 (0520) by adding cell-based preparations to the list of preparations to which the monograph does not
- 19 necessarily apply, and if so, evaluation of the need for a general Ph. Eur. text dealing with cell-based
- 20 preparations
- 21 • Drafting and revision of other texts in the field of cell therapy products

22 *Profile for experts*

- 23 • Current expertise in analytical methods related to the development and quality control of cell therapy
- 24 products and/or tissue-engineered products and/or to the quality control of tissues for human use
- 25 • Several years of experience in one or more of the following fields:
 - 26 ○ Development of cell therapy products and/or tissue-engineered products
 - 27 ○ Quality control of cell therapy products and/or tissue-engineered products in a pharmaceutical
 - 28 manufacturing setting or in a hospital environment and/or microbiological control of tissues
 - 29 and organs used for human transplantation
 - 30 ○ Assessment of applications for marketing authorisation of cell therapy and/or tissue-
 - 31 engineered products
 - 32 ○ Market surveillance of the quality of cell therapy products, tissue-engineered products and/or
 - 33 tissues and organs used for human transplantation in a regulatory authority
 - 34 ○ Pharmaceutical quality control in an independent testing laboratory
 - 35 ○ Development of methods (e.g. microbiological methods) to control cell therapy products
 - 36 and/or tissue-engineered products and/or tissues and organs used for human transplantation in
 - 37 a research and development environment

38

39 **DIA Working party (Dialysis)**40 *Terms of reference*

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

42 *Profile for experts*

- 43 • Current expertise in the field of preparations for dialysis
- 44 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 45 monographs
- 46 • Several years of experience in one or more of the following fields:

- 1 ○ Quality control of preparations for dialysis in a pharmaceutical manufacturing setting or in a
- 2 hospital
- 3 ○ Quality control of preparations for dialysis in a regulatory authority
- 4 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
- 5 agency
- 6 ○ Quality control of preparations for dialysis in an independent testing laboratory
- 7 ○ Method development and verification in a regulatory authority

8 **EXP Working Party (Excipient performance)**

9 *Terms of reference*

- 10 • Drafting and maintaining the FRC (Functionality Related Characteristics) sections of monographs on
- 11 excipients to reflect current best practices, in consultation with the appropriate Groups of Experts or
- 12 Working Parties of the Ph. Eur.
- 13 • Review, where necessary, and maintenance of general chapter 5.15 FRCs of excipients to align it with
- 14 current regulatory guidance (e.g. ICH Q8 guideline)
- 15 • Drafting and maintenance of the text on Co-processed excipients
- 16 • Review pharmacopoeial and other regulatory texts on general information on excipients with a view to
- 17 proposing necessary additions and updates, where relevant

18 *Profile for experts*

- 19 • Current expertise in analytical methods (especially those included in the Ph. Eur. section 2.9.
- 20 Pharmaceutical technical procedures), related to control of excipients and in development of control
- 21 methods
- 22 • Several years of experience in one or more of the following fields:
- 23 ○ Quality control of excipients in a bulk or pharmaceutical manufacturing setting
- 24 ○ Pharmaceutical and excipient research and development
- 25 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
- 26 agency
- 27 ○ Development of control methods for excipients, comprising methods to determine excipient
- 28 performance (FRCs) in a research and development environment
- 29 ○ Pharmaceutical quality control in an independent testing laboratory

30 **EXT Working Party (Extracts)**

31 *Terms of reference*

- 32 • Revision of the general monograph on *Extracts (0765)* with the aim of clarifying/improving the
- 33 definitions and requirements of the different types of extracts whilst maintaining the established
- 34 classification system of extracts

35 *Profile for experts*

- 36 • Several years of experience in one or more of the following fields:
- 37 ○ Assessment of the relevant parts of applications for marketing authorisation of herbal
- 38 medicinal products within a medicines agency
- 39 ○ Production or quality control of extracts for further use in herbal medicinal products
- 40 ○ Production or quality control of herbal medicinal products containing extracts

41 **GEL Working Party (Gelatin)**

42 *Terms of reference*

- 43 • To provide support and advice in case of questions raised by e.g. users in the field of gelatin
- 44 • International harmonisation of monographs on Gelatin

1 *Profile for experts:*

- 2 • Current expertise in pharmaceutical analytical methods, related to quality control of gelatin and in
- 3 development of control methods
- 4 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 5 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 6 texts.
- 7 • Several years of experience in one or more of the following fields:
- 8 ○ Quality control in a pharmaceutical or bulk manufacturing setting (gelatin or use of gelatin)
- 9 ○ Market surveillance of quality in a regulatory authority
- 10 ○ Pharmaceutical quality control in an independent testing laboratory
- 11 ○ Method development and verification in a regulatory authority
- 12 ○ Development of pharmaceutical control methods using near infrared spectrometry for gelatin
- 13 identification

14 **GLS Working Party (Glass Containers)**

15 *Terms of reference*

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

17 *Profile for experts*

- 18 • Current expertise in the production of glass containers, analytical methods, related to quality control of
- 19 glass containers and in development of control methods
- 20 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 21 general chapters
- 22 • Several years of experience in one or more of the following fields:
- 23 ○ Quality control in a pharmaceutical manufacturing setting for control of glass containers
- 24 ○ Production and/or Quality control of glass containers in an industrial setting
- 25 ○ Market surveillance of quality in a regulatory authority
- 26 ○ Pharmaceutical quality control in an independent testing laboratory
- 27 ○ Development of control methods for control of glass containers in a research and development
- 28 environment

29 **GTP Working Party (Gene Therapy Products)**

30 *Terms of reference*

- 31 • Revision of the general chapter 5.14 *Gene transfer medicinal products for human use* (raw materials
- 32 part) to account for the chapter 5.2.12 *Raw materials of biological origin for the production of cell-*
- 33 *based and gene therapy medicinal products*; Evaluation of the general chapter 5.14 in the view of
- 34 development in the field within last decade and its potential revision
- 35 • Participation in elaboration/revision of transversal texts elaborated by other Groups of Experts or
- 36 Working Parties, (e.g. general chapter 2.6.35 Quantification and characterisation of residual host cell
- 37 DNA)
- 38 • Drafting and revision of other texts in the field of gene therapy

39 *Profile for experts*

- 40 • Current expertise in analytical methods related to development and quality control of gene therapy
- 41 products and in development of control methods
- 42 • Several years of experience in one or more of the following fields:
- 43 ○ Development of gene therapy products
- 44 ○ Quality control of gene therapy products in a pharmaceutical manufacturing setting or in a
- 45 hospital environment
- 46 ○ Assessment of applications for marketing authorisation of gene therapy products
- 47 ○ Marketing surveillance of quality in a regulatory authority

- 1 ○ Pharmaceutical quality control in an independent testing laboratory
2 ○ Development of methods for control of gene therapy products in a research and development
3 environment
4

5 **HM Working Party (Heavy metals)**

6 *Terms of reference*

- 7 • Drafting and revision of the general chapter 5.20 Elemental impurities. In this context, identification of
8 technical issues which need to be addressed by ICP working party such as sample preparation and
9 instrumental determination by *atomic emission spectrometry, inductively coupled plasma - atomic*
10 *emission spectrometry* and *inductively coupled plasma - mass spectrometry* and which would require an
11 update of the respective general methods
12 • International harmonisation of chapter 2.4.20 (PDG item G-07)

13 *Profile for experts*

- 14 • Up-to-date substantial expertise in pharmaceutical analytical methods, related to quality control of
15 active substances and excipients allowing a holistic view on the occurrence of metals from either
16 synthesis or contamination
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 synthetic and semi-synthetic organic products in a bulk manufacturing
20 setting
21 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
22 agency
23 ○ Pharmaceutical quality control of active substances and /or excipients in an independent
24 testing laboratory specialised in testing for metals as residues from synthesis or contaminants

25 **HMM Working Party (Homoeopathic Manufacturing Methods)**

26 *Terms of reference*

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

28 *Profile for experts*

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

36 **HOM Working Party (Homoeopathic Raw Materials and Stocks)**

37 *Terms of reference*

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

39 *Profile for experts*

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

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

9 **ICP Working Party (Inductively-Coupled Plasma)**

10 *Terms of reference*

- 11 • Drafting and revision of texts in the field of *atomic absorption spectrometry, atomic emission*
- 12 *spectrometry, inductively coupled plasma - atomic emission spectrometry* and *inductively coupled*
- 13 *plasma - mass spectrometry*

14 *Profile for experts*

- 15 • Current expertise in the development, and application of analytical procedures involving the above
- 16 mentioned techniques
- 17 • Several years of experience in one or more of the following fields:
- 18 ○ Quality control of herbal drugs, herbal drug preparations, synthetic, semi-synthetic, natural
- 19 origin, biological or biotechnological products in a pharmaceutical setting
- 20 ○ Quality control in a regulatory authority or an independent testing laboratory

21 **INH Working Party (Inhalations)**

22 *Terms of reference*

- 23 • Drafting and revision of monographs and general chapters in the field of preparations for inhalation
- 24 • International harmonisation of related general chapters

25 *Profile for experts*

- 26 • Current expertise in pharmaceutical analytical methods, related to quality control of preparations for
- 27 inhalation and in development of control methods
- 28 • Several years of experience in one or more of the following fields:
- 29 ○ Quality control of preparations for inhalation in a pharmaceutical manufacturing setting
- 30 ○ Market surveillance of quality in a regulatory authority
- 31 ○ Assessment of applications for marketing authorisation of preparations for inhalation within an
- 32 agency
- 33 ○ Development of control methods for control of preparations for inhalation in a research and
- 34 development environment
- 35 ○ Pharmaceutical quality control in an independent testing laboratory
- 36 ○ Method development and verification in a regulatory authority

37 **LEC Working Party (Lecithins)**

38 *Terms of reference*

- 39 • Drafting and revision of monographs in the field of lecithins

40 *Profile for experts*

- 41 • Current expertise in pharmaceutical analytical methods, related to quality control of lecithins and in
- 42 development of control methods
- 43 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 44 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 45 texts/
- 46 • Several years of experience in one or more of the following fields:

- 1 ○ Quality control of lecithins in a pharmaceutical or bulk manufacturing setting
- 2 ○ Market surveillance of quality in a regulatory authority
- 3 ○ Pharmaceutical quality control in an independent testing laboratory
- 4 ○ Development of control methods for lecithins in a research and development environment
- 5 ○ Method development and verification in a regulatory authority

6 MAB Working Party (Monoclonal Antibodies)

7 *Terms of reference:*

- 8 • To undertake a pilot phase to elaborate general methods for analysis of monoclonal antibodies and
9 individual monographs using the multisource approach (according to document PA/PH/Exp. MAB/T
10 (14) 1)
- 11 • Drafting and revision of texts in the field of monoclonal antibodies

12 *Profile for experts*

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

26 MG Working Party (General methods)

27 *Terms of reference*

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

36 *Profile for experts*

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

1 agency

2 **MYC Working Party (Mycoplasma)**

3 *Terms of reference*

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

6 *Profile for experts*

- 7 • Current expertise in mycoplasma testing of medicinal products and in development of control methods
8 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
9 monographs,
10 • Several years of experience in one or more of the following fields:
11 ○ Mycoplasma testing in a pharmaceutical manufacturing setting
12 ○ Mycoplasma testing in an official control laboratory for medicines
13 ○ Mycoplasma testing in an independent testing laboratory
14 ○ Development of test methods for mycoplasmas in a research and development environment

15 **NBC Working Party (Non-Biological Complex Drugs)**

16 *Terms of reference*

- 17 • Elaboration and revision of monographs on non-biological complex drugs (e.g. nanoparticle
18 dispersions, like for example iron sucrose concentrated solution)

19 *Profile for experts*

- 20 • Current expertise in the development and/or quality control of non-biological complex drugs and in
21 development of control methods
22 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
23 monographs,
24 **Essential:** Active involvement in laboratory verification of test methods and drafting of texts and
25 • Several years of experience in one or more of the following fields:
26 ○ Quality control in a pharmaceutical manufacturing setting or in an independent testing
27 laboratory (e.g. Market surveillance of quality in a regulatory authority)
28 ○ Pharmaceutical and/or analytical development related to respective formulations
29 ○ Assessment of the relevant parts of applications for marketing authorisation within a medicines
30 agency

31 **P4BIO Working Party (P4 Bio)**

32 *Terms of reference*

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

34 *Profile for experts*

- 35 • Group P4Bio is restricted to regulators from Ph. Eur. Member states however industry representatives
36 may be invited to contribute by submission of data and interaction with the group via the Secretariat
37 • Current expertise in pharmaceutical analytical methods, related to quality control of biologicals and in
38 development of control methods
39 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
40 monographs or access to licensing files (essentially originating from CAP), **Essential:** Active
41 involvement in laboratory verification of test methods and drafting of texts and
42 • Several years of experience in one or more of the following fields:
43 ○ Quality control in a regulatory authority
44 ○ Assessment of the relevant parts (biologicals) of applications for marketing authorisation
45 ○ Market surveillance of quality in a regulatory authority

1 **PA Working Party (Pyrrolizidine alkaloids)**

2 *Terms of reference*

- 3 • Drafting of a general chapter allocated to the group by the Commission in the field of pyrrolizidine
4 alkaloids.
5 • Maintenance of the list of PA alkaloids which may be covered by the general chapter on PA alkaloids.

6 *Profile for experts*

- 7 • Current expertise in PA analysis, related to quality control of herbal drugs and in development of
8 control methods.
9 • Access to laboratory facilities for quality control. Essential: active involvement in laboratory
10 verification of methods and drafting of texts
11 • Several years of experience in one or more of the following fields:
12 ○ Quality control of herbals in a pharmaceutical or bulk manufacturing setting, in a regulatory
13 authority or in any other specialised testing laboratory;
14 ○ Development and/or lab verification of control methods for analysis of pyrrolizidine alkaloids
15 in a research and development environment or in a regulatory authority.

16 **PaedF Working Party (European Paediatric Formulary)**

17 *Terms of reference*

- 18 • Elaboration, and revision of monographs on paediatric preparations according to criteria and guidelines
19 approved by the CD-P-PH
20 • Establishment and maintenance of a Technical Guide for the elaboration and maintenance of monographs on
21 paediatric preparations

22 *Profile for experts*

- 23 • Current expertise in development of paediatric preparations (including toxicologists)
24 • Current expertise in analytical methods related to quality control of ingredients (APIs and excipients)
25 and preparations and in the development of such methods; Access to laboratory facilities for
26 verification of methods proposed for inclusion in monographs
27 • Current expertise in clinical/pharmacological treatment of several paediatric age groups
28 • Several years of experience in one or more of the following fields:
29 ○ Pharmaceutical development and/or manufacturing of paediatric preparations (in a community
30 or hospital pharmacy, research unit, or in pharmaceutical industry)
31 ○ Method development and verification of medicinal preparations in a pharmaceutical
32 manufacturing setting (including research and development), in a regulatory authority, in a
33 community or hospital pharmacy or in an independent testing laboratory
34 ○ Market surveillance of quality in a regulatory authority
35 ○ Assessment of the relevant parts of applications for marketing authorisation of paediatric
36 medicinal products (including safety assessment)
37 ○ Elaboration/assessment of monographs for national paediatric formularies
38 ○ Clinical/pharmacological treatment of children belonging to several age groups

39 **PAT Working Party (Process Analytical Technology)**

40 *Terms of reference*

- 41 • Review and revision of existing general monographs and chapters of existing pharmacopoeial texts in
42 view of needs arising from Process Analytical Technology (PAT), Continuous Manufacturing (CM),
43 Real Time release testing (RTRT) or Quality by Design (QbD) concepts
44 • Identify and discuss the implication of the above mentioned concepts on the texts of European
45 Pharmacopoeia and make proposals to the Commission where needed
46 • Support and advise other group of experts and working parties where elements of the above mentioned
47 concepts are concerned.

1 *Profile for experts*

- 2 • Expertise in chemical or pharmaceutical development and control methods applied during manufacture
- 3 and to active substances or finished pharmaceutical preparations
- 4 • Several years of experience in one or more of the following fields
- 5 ○ Development of pharmaceutical preparations using PAT, CM, RTRT or QbD concepts in an
- 6 industrial setting
- 7 ○ Assessment of the relevant parts of applications for marketing authorisation containing PAT,
- 8 CM, RTRT or QbD concepts within a medicines agency
- 9 ○ Development of control strategies including PAT, CM, RTRT or QbD concepts approaches for
- 10 testing of active substances or pharmaceutical preparations
- 11 ○ Development of pharmaceutical preparations using modelling and chemometrics associated
- 12 with the analytical aspects for PAT

13 **POW Working Party (Powder Characterisation)**

14 *Terms of reference*

- 15 • Drafting and revision of general chapters in the field of powder characterisation
- 16 • International harmonisation of general chapters

17 *Profile for experts*

- 18 • Current expertise in methods for powder characterisation, related to quality control of active substances
- 19 and excipients and in development of control methods
- 20 • Several years of experience in one or more of the following fields:
- 21 ○ Quality control of active substances and excipients in a pharmaceutical manufacturing setting
- 22 ○ Assessment of the relevant parts of applications for marketing authorisation
- 23 ○ Market surveillance of quality in a regulatory authority
- 24 ○ Development of methods for characterisation of powders in a research and development
- 25 environment
- 26 ○ Pharmaceutical quality control in an independent testing laboratory

27 **PRP Working Party (Precursors for Radiopharmaceutical Preparations)**

28 *Terms of reference*

- 29 • Drafting and revision of texts in the field of non-radioactive precursors for radiopharmaceutical
- 30 preparations

31 *Profile for experts*

- 32 • Expertise in chemical, pharmaceutical and radiopharmaceutical methods, related to quality control of
- 33 radiopharmaceutical preparations and their precursors
- 34 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 35 monographs. **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 36 texts
- 37 • Several years of experience in one or more of the following fields:
- 38 ○ Quality control of radiopharmaceutical preparations and their precursors
- 39 ○ Quality control of synthetic organic and/or inorganic products in a chemical or pharmaceutical
- 40 setting
- 41 ○ Quality control in an independent testing laboratory
- 42 ○ Development of analytical procedures for the control of radiopharmaceutical preparations and
- 43 their precursors

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

45 *Terms of reference*

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

- 1 • Advising the Commission on acceptance criteria for pesticide residues to be included in monographs
- 2 • Maintenance of the list of pesticides tabled in general chapter on pesticide residues

3 *Profile for experts*

- 4 • Current expertise in pesticide analysis, related to quality control of active substances and excipients and
5 in development of control methods
- 6 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
7 monographs
- 8 • Several years of experience in one or more of the following fields:
 - 9 ○ Quality control for pesticide residues in herbals in a pharmaceutical or bulk manufacturing
10 setting
 - 11 ○ Market surveillance of quality in a regulatory authority
 - 12 ○ Pharmaceutical quality control in an independent testing laboratory
 - 13 ○ Development of control methods for analysis of pesticide residues in a research and
14 development environment

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

16 *Terms of reference*

- 17 • Drafting and revision of general chapters in the fields of:
 - 18 ○ Measurement techniques relying on spectroscopy, with the exception of specific spectroscopic
19 techniques where the drafting and revision of general chapters is allocated to other, more
20 specialised groups of experts and working parties.
 - 21 ○ Chemical imaging techniques, e.g. spectral and multispectral imaging, electron microscopy,
22 field effect and atomic force microscopies, optical and X-ray tomography, etc.
 - 23 ○ Chemometrics and data sciences techniques relying on multivariate data analysis, numerical
24 methods, algorithmics, data modelling, data mining, artificial intelligence, etc., and image
25 analysis techniques.
- 26 • to support and advise other group of experts and working parties where elements of the above
27 mentioned measurement and data analysis techniques are concerned and where relevant.

28 *Profile for experts*

- 29 • Current expertise in spectroscopy related to quality control of active substances, excipients or products,
30 in development of analytical control methods.
- 31 • Ideally, access to laboratory facilities for verification and validation of methods proposed for inclusion
32 in general chapters and monographs. **Essential:** Active involvement in laboratory verification of test
33 methods and drafting of texts Several years of experience in one or more of the following fields:
 - 34 ○ Use of spectroscopic techniques for pharmaceutical quality control in a pharmaceutical
35 manufacturing setting, a regulatory authority or an independent testing laboratory.
 - 36 ○ Development of pharmaceutical in-, on-, or at-line control methods using spectroscopic or
37 imaging techniques or chemometrics and data analysis, in a research and development
38 environment.
 - 39 ○ Assessment of applications for marketing authorisation.
 - 40 ○ Use of spectroscopic techniques for the market surveillance of the quality of pharmaceutical
41 substances or products.

42 **SIT Working Party (Second identification test)**

43 *Terms of reference*

- 44 • To support and advise the Commission, Groups of Experts or Working Parties on revision/suppression
45 of existing identification series, notably arising from the REACH regulation, where relevant.
46 Propose to the Commission further items for the work programme (such as replacements of methods not
47 in line with the available instrumentation in pharmacies or monographs with missing second
48 identification)

1 *Profile for experts*

- 2 • Pharmacists regularly involved in preparation of extemporaneous or stock preparation of medicinal
- 3 products in community pharmacies or hospitals as well as in the analysis of the pharmaceutical
- 4 substances used
- 5 • Pharmacists or chemists with special interest/expertise in analytical methods commonly available in
- 6 pharmacies
- 7 • Members of a regulatory authority

8 **ST Working Party (Standard Terms)**9 *Terms of reference*

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

14 *Profile for experts*

- 15 • Current expertise in pharmaceutical dosage forms
- 16 • Several years of experience in one or more of the following fields:
 - 17 ○ Assessment of the pharmaceutical development part of applications for authorisation of
 - 18 medicinal products
 - 19 ○ Development of general monographs for dosage forms (group of experts or national
 - 20 pharmacopoeia secretariat)
 - 21 ○ Experience in formulation of medicinal products
- 22 • Members of the working party may be from a regulatory authority, universities

23 **SUT Working Party (Sutures)**24 *Terms of reference*

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

26 *Profile for experts*

- 27 • Expertise in pharmaceutical analytical methods, related to quality control of sutures and in development
- 28 of control methods
- 29 • Several years of experience in one or more of the following fields:
 - 30 ○ Quality control of sutures
 - 31 ○ Development of methods for control of sutures

32 **TCM Working Party (Traditional Chinese Medicines)**33 *Terms of reference*

- 34 • Drafting and revision of texts in the field of herbal drugs and herbal drug preparations preferably based
- 35 on the principle of adapting/improving existing monographs or methods to control herbal drugs used in
- 36 Traditional Chinese Medicines (TCM)
- 37 • Drafting general chapters related to the specific needs of TCM herbal drugs

38 *Profile for experts*

- 39 • Current expertise in pharmaceutical analytical methods, related to quality control of herbal drugs and
- 40 herbal drug preparations and in development of control methods
- 41 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 42 monographs
- 43 • Several years of experience in one or more of the following fields:
 - 44 ○ Quality control of herbal drugs/herbal drug preparations in a manufacturing setting
 - 45 ○ Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent
 - 46 testing laboratory

- 1 ○ Development of methods for control of herbal drugs
- 2 ○ Involvement in market surveillance or regulatory oversight of imported TCM herbal drugs
- 3 • **Essential:** Active involvement in laboratory verification of test methods for TCM herbal drugs and in
- 4 drafting of texts.
- 5 • Development of chromatographic separation systems for herbal drug constituents
- 6 • Knowledge in cultivation, harvesting, processing and use of TCM herbal drugs

7 **VIT Working Party (Vitamins)**

8 *Terms of reference*

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

10 *Profile for experts*

- 11 • Current expertise in pharmaceutical analytical methods, related to quality control of vitamins and
- 12 excipients and in development of control methods. *The need of a specialist for vitamin D type*
- 13 *substances is highlighted*
- 14 • Access to laboratory facilities for verification and validation of methods proposed for inclusion in
- 15 monographs, **Essential:** Active involvement in laboratory verification of test methods and drafting of
- 16 texts.
- 17 • Several years of experience in one or more of the following fields:
- 18 ○ Quality control of vitamins in a pharmaceutical or bulk manufacturing setting
- 19 ○ Market surveillance of quality in an official control laboratory for medicines
- 20 ○ Pharmaceutical quality control in an independent testing laboratory
- 21 ○ Development of methods for control of vitamins in a research and development environment
- 22 ○ Method development and verification in a national pharmacopoeia laboratory
- 23 ○

24 **WAT Working Party (Water)**

25 *Terms of reference*

- 26 • Drafting and revision of texts in the field of water
- 27 • International harmonisation of relevant texts

28 *Profile for experts*

- 29 • Current expertise in analytical methods applicable in water analysis in development of control methods
- 30 • Several years of experience in one or more of the following fields:
- 31 ○ Quality control of water in a pharmaceutical manufacturing setting
- 32 ○ Inspection of manufacturing sites
- 33 ○ Pharmaceutical quality control in an independent testing laboratory
- 34 ○ Development of methods for control of pharmaceutical waters in a research and development
- 35 environment

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