

**The Official Medicines Control
Laboratories - OMCL**

1995 - 2005

AN INTEGRATED EFFICIENT PAN EUROPEAN NETWORK

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Biological Standardisation and OMCL Network**

OMCL Network - history

- **September 1994 : in collaboration with EU a meeting was organised by EDQM in Strasbourg with the Heads of the control Laboratories in Europe the aim of which was to make an “ Inventory of the needs for a harmonised sampling and testing of medicines in Europe “
The outcome was to decide to initiate the building of the OMCL Network**

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OMCL Network - history (2)

In fact the need was already there

- **in early 1990s with the implementation of the directives on blood/plasma derivatives and vaccines for human use as it included for the first time**

MUTUAL RECOGNITION

of Laboratories results namely for the Batch Release by Authorities

hence the need to structure and codify the system

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- **The catalogue of actions to be undertaken was immense so was the enthusiasm of all partners involved to find a solution**

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OMCL Network - the building phase

- **Learning to work together**
 - **Meetings**
 - **Defining**
 - **Rules and structures**
 - **Working methods**
 - **Standards : guidelines, procedures**
 - **Communication tools**

based on OMC (open method of coordination)

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OMCL Network - the « constitution »

- **Rules and structure**
 - **Definition of an OMCL**
 - **Governmental « official » laboratory**
 - **Testing independent from manufacturer = absence of conflict of interest and confidentiality in cases of subcontracting**
 - **Terms of reference of the Network**
 - **Terms of reference of the different working groups**

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OMCL Network - functioning

- **Organisation and communication tools**
- Ongoing exchange of data/results/know-how through**
 - **Annual meeting**
 - **Exchange of activity reports and working programmes, methods related issues and new developments**
 - **Thematic meetings (QA, methods/products linked)**
 - **Drafting groups - technical**
 - **Advisory groups - structural**

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OMCL Network - working methods

- **based on harmonised consensual approaches defined in**
 - **Procedures**
 - **Guidelines**
 - **Position papers ...**
 - **Elaborated by specialists (drafting groups)**
 - **Adopted by plenary annual OMCL assembly after consultation of concerned parties**
- **Quality Assurance is a pre-requisite**

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OMCL Network - QA approach

- a Common QA standard ISO 17025 complemented with guidelines dealing with the specificities of OMCLs (see QA booklet)
 - Specific programme of assistance and auditing in place to ensure appropriate implementation and maintenance of the standard - similar to accreditation
 - Cooperation with EA is developing
- a customised programme of Proficiency testing PTS in different field of activities (physico/chemical, pharmaceutical, biological methods) also opened since 2000 to private laboratories

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OMCL Network - QA approach(2)

- QA is a tool to ensure
 - Credibility
 - Traceability
 - Competence
 - Good results

but is not an activity

**THE ROLE OF THE OMCL IS TO
CONTROL MEDICINAL PRODUCTS**

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OMCL Network today

- **Consists of 85 members from 34 Member States - PhEur convention / CoE + associated countries CDN, AUS,**

More than 1500 experts covering all different areas of human and veterinary medicines

Biologicals, pharmaceuticals, immunobiologicals and blood products, herbals, radiopharmaceuticals, advanced therapies ...etc

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OMCL Network today

- **The OMCL Network is not a stand-alone body but very interactive with all partners**

– **Regulators**

- **Licensing, authorities at European (EMEA) and national level**

- **Assessors and inspectors**

– **Manufacturers**

In EUROPE but also beyond

Canada, Australia, Morocco and more general with different WHO programmes QA, ECBS ...

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OMCL Network now

- **A Forum for various activities**
 - **At European Union level**
 - **OMCLs are involved in controls**
 - **for Batch Release (OCABR biologicals for human use) and**
 - **post marketing surveillance (compliance testing) for**
 - **CAPs in close collaboration with EMEA**
 - **MRPs trial phase**
 - **OCABR for IVMPs under discussion**
 - but also in**
 - **Pre-authorisation testing for new methods**

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OMCL Network today

- **General pan European Quality Control activities**
 - **Market surveillance (MSS)**
 - **QA/QMS**
- **Characterisation of ref. materials-CRS/BRP**
- **Validation of methods (introduced later in the PhEur)**
 - **Solvent determination (safety)**
 - **NAT blood borne viruses (safety)**
 - **Alternatives to animal testing (potency/safety)**

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OMCL Network today

- **Legal basis included in both EU codes for Human and veterinary medicines and regulation**
- **Directives 2001/83 + 2004/27 Articles 111, 114 and 19**
- **Directives 2001/82 + 2004/28 Articles 80, 82 and 29**
- **Reg. 726/2004 Article 57 r)**

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OMCL Network

The criteria driving the system nowadays

- **MUTUAL CONFIDENCE**
- **TRANSPARENCY**
- **WORK SHARING**
- **COST EFFICIENCY**
- **COOPERATIVE**
- **SYNERGIE WITH ALL
NATIONAL/INTERNATIONAL PARTNERS**

**IN A CONTINUOUSLY EVOLVING
ENVIRONMENT**

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OMCL Network

- **OMCLs = 1500 experts from 85 Members**
- **EDQM**
 - **A team of dedicated 17 persons in Div.IV to coordinate, organise and elaborate on the different, numerous and growing activities but also a lot of others colleagues are key players in the shadow**
Div.III:laboratories bio and pharm/chem., the QA unit, the centre for references and dispatch unit, publication div. and conference/public relation unit
 - **The former colleagues who have left us**
- **THE SPONSORS EU COMMISSION DG. ENTERPRISE and CoE**

OUR WARMEST THANKS

- **The birthday party is now open !!**

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OMCL information day :

Quality Assurance policy developed within the network

Agence française
de sécurité sanitaire
des produits de santé



Speaker :

L. Lempereur, Quality Coordinator – DLC

QA policy developed within the network



3 main parts :

- **Interest to develop a quality policy for an OMCL**
- **Quality standard applied and strategy developed by the network**
- **French OMCL example : add value and future expectations**

Interest for an OMCL



- **Objectives and add value of a European OMCLs network :**
 - to identify and to share competencies between different laboratories
 - to avoid duplication of tests
 - to maintain a mutual recognition level of results
- **In this context, the development of a strong quality management system is strategic for an OMCL**
- **Main tool for an OMCL to give confidence to its different partners**

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OMCL information day : QA policy developed within the network – 27 March 2005 - Rome

Interest for an OMCL



- **Clearly identify the OMCL's partners as « clients » with different expectations to take into account :**
others OMCLs in the network, national authority, EMEA, WHO and manufacturers
- 3 main objectives**
- to improve the accuracy and the reproducibility of results
 - to ensure the same transparent approach whatever the product and the manufacturer :
clear documented process from the demand to the results.
 - to keep a perfect traceability of activities in order to prove that quality requirements have been followed and to be able to perform retest in the same conditions in case of complaints

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Quality standard applied



- **First quality meeting of the network in 1996 :
adoption of the norm EN 45001 as OMCL quality standard**
- **Replaced in 2000 by the ISO 17025 quality standard for assay laboratories**
 - Base for technical accreditations
 - 2 main parts
 - First, with quality management requirements (ISO 9001)
 - Second, with detailed technical requirements
 - More requirements concerning the validation of methods and the uncertainty of measurement, but also internal audits and service to the clients

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Strategy developed in the network



- **Elaboration of EDQM quality guidelines :
common approach in front of some ISO 17025 requirements
which are not always obvious for some specific OMCLs activities**
 - Validation of Analytical Procedures
 - Evaluation and Reporting of Results
 - Uncertainty of Measurement
 - Qualification of Equipment
 - Archiving
- **Draft elaboration by a working group : members from different OMCLs**
Wide distribution in the network for comments
Final approbation during a quality meeting

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Strategy developed in the network



- **Organization of quality training sessions performed by OMCLs members for others or by external consultants**

Quality management issues, e.g. : internal audits, corrective and preventive actions, management review ...

Technical issues, e.g. : validation of methods, measurement uncertainty estimate ...

- **Organization of Proficiency Testing Studies**
Annual planning for physico-chemical and biological methods taking into account OMCLs wishes

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Mutual joint audits



- **System of mutual joint audits or visits in place since 1998**
- **Participation on voluntary basis**
- **Peer review by colleagues from the network**

Visits : external help to put in place a quality system
Replaced in 2004 by tutorials on specific items

Audits : external review of the OMCL quality system
according to ISO 17025 requirements.

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Mutual joint audits



- **Team of 4 auditors**
 - 2 auditors in charge of quality management items (one of them from EDQM : audit coordinator)
 - 2 auditors competent for technical activities audited
- **Auditor trainings regularly organized by EDQM**
- **Each step of the MJA process documented in SOPs and recorded with specific forms**
 - Audit request
 - Audit notification
 - Audit plan
 - Audit report

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Mutual joint audits



- **Elaboration of a standard audit checklist from ISO 17025 : same requirements whatever the audit team**
- **Specific animal housing and testing checklist**
- **Recording of all non-conformity detected. Auditees have to develop corrective actions in a defined delay**
- **Follow up of corrective actions efficiency coordinated by EDQM**
- **Archiving of final report by EDQM. Confidentiality agreements signed by auditors**

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French OMCL example



- **Active participation to the network since the beginning**
guidelines elaboration
trained auditors for MJA
regular MJA on our 3 sites, covering all our activities

| | <u>Visits</u> | <u>Audits</u> |
|-------------------------|--------------------|----------------------------|
| Lyon Site | 2000 | 2001 |
| Montpellier Site | 2000 | 2002 2004 |
| Saint-Denis Site | 2000 - 2001 | 2001 2004 |

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French OMCL example



- **External pressure to move from basic quality assurance to a quality management system based on an efficient involvement of the management**
- **Possibility to obtain information from colleagues who share the same activities. Solutions adapted and efficient. Positive exchange of experiences, complementary with trainings**
- **Optimization of the whole staff adhesion to the quality policy. Recognition of our competences at an European level by specialists in the same field of activities**

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Conclusion



Quality policy developed in the network contributes to :

- **an easy and cheap accessibility to general education and trainings concerning quality matters**
- **a positive pressure to improve organization and technical competencies of OMCLs and to reach the same quality level necessary for mutual recognition**
- **a cheap and very adapted tool to prove technical competencies. Complementary to accreditations given by national bodies with stricts and often limited scopes for heavy costs.**

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Expectations for the future



- **To maintain the global approach with EDQM, covering all our lab activities with periodical MJA on our 3 sites (12 technical units)**

Impossible to maintain accreditations for a so wide range of activities : Cost/Benefit ratio too heavy

- **To develop some « combines audits » where OMCL network members and European accreditation body members share competencies in order to obtain formal accreditations on OMCLs specific scopes (e.g. : vaccines or blood products batch release)**

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Role and importance of proficiency testing

Pharmaceutical methods

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Proficiency testing

Proficiency testing is the use of inter-laboratory comparison for the determination of laboratory testing or measurement performance

Participation in proficiency testing schemes provides laboratories with an objective means of assessing and demonstrating the reliability of the data they are producing

It should be used as a complement of the QA system in place as requested by the standard ISO 17025

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EDQM PTS Scheme: main steps

- 1) Appointment of scientific advisor
- 2) Procurement of materials and information
- 3) Feasibility study
- 4) Processing of material
- 5) Verification of processed material
- 6) Preparation of the protocol
- 7) Dispatching of samples and protocol

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EDQM PTS Scheme: main steps

- 8) Experimental phase (labs testing)
- 9) Raw data collection and coding at EDQM Div IV
- 10) Statistical evaluation
- 11) Reporting (preliminary and final)
- 12) Attestation of participation
- 13) Follow up: Corrective/preventive actions

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Statistical evaluation

Proficiency of the lab assessed on the basis of:

- Precision (repeatability) → relative standard deviation (RSD)
- Accuracy (closeness of agreement between assigned value and the mean value found) → z-score

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EDQM PTS Scheme: some data

- Scheme initiated in 1995 (OMCLs + EDQM: Div IV and Div III laboratory)
- Open to non-OMCL laboratories since 2000
- 45 pharmaceutical PTS carried out until now
- 5-6 studies/year on routine techniques

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EDQM PTS Scheme:some data

- Average of 45 participants/study
- Use of compendial methods: Ph. Eur., (BP and USP for finished products only)
- 10 studies carried out on finished products (tablets, suppositories, injections)

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PTS studies performed

- Liquid chromatography: 12
- Titrations: 9
- UV-VIS spectrophotometry: 6
- Water content: 4
- Gas Chromatography: 4

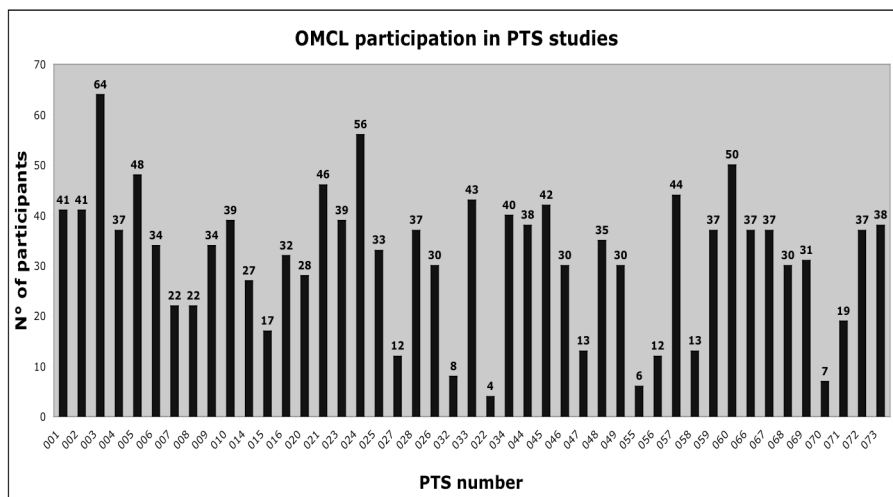
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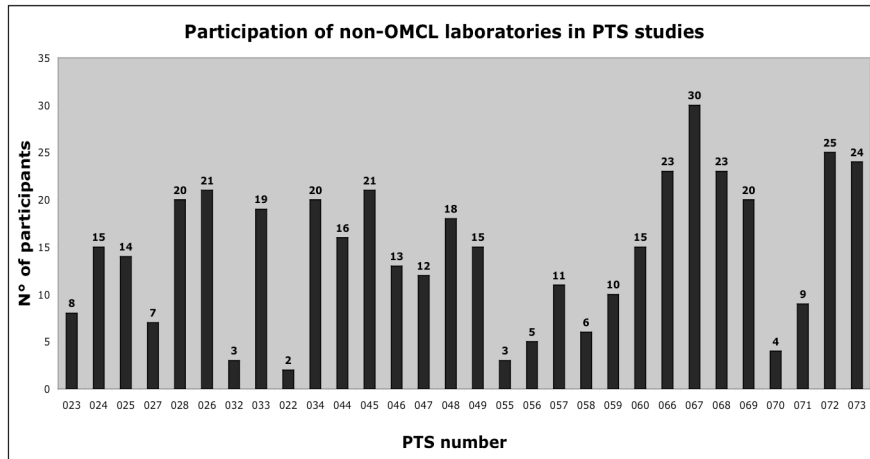
PTS studies performed

- Atomic Absorption Spectrometry: 3
- Dissolution test: 3
- Loss on drying: 2
- Capillary electrophoresis: 2

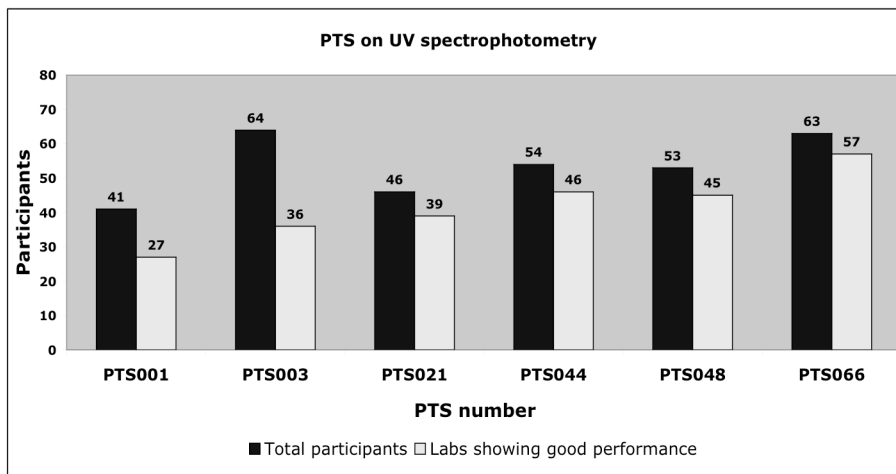
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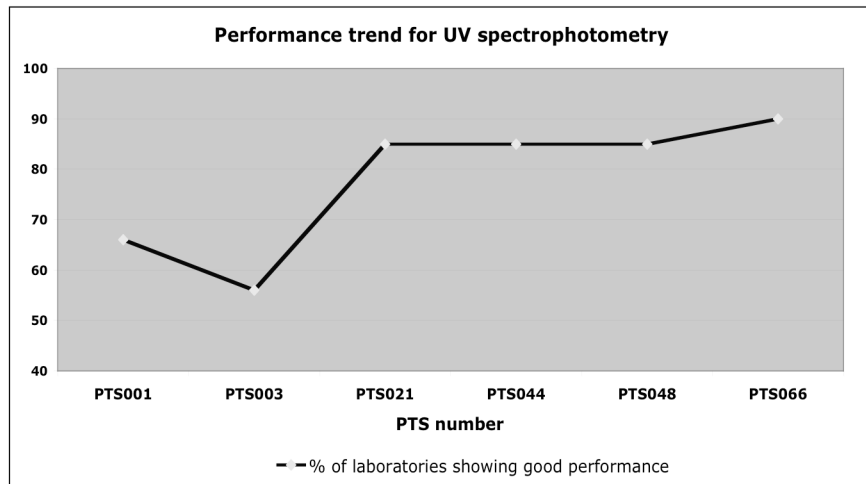
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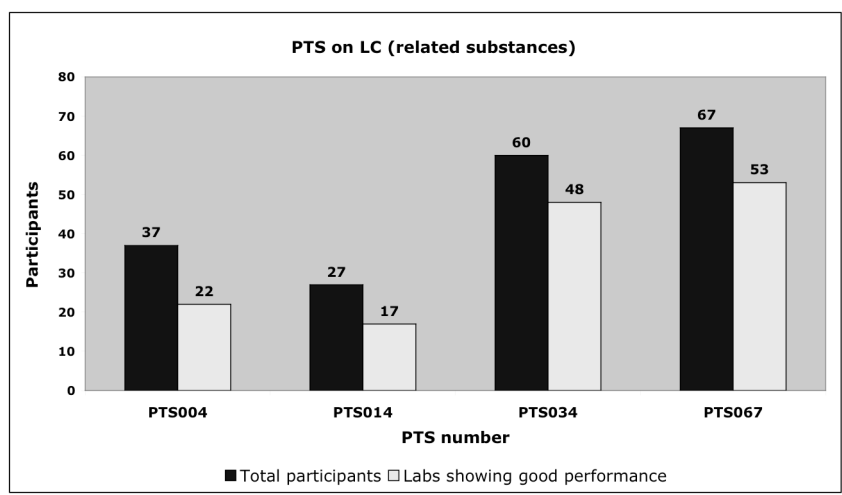
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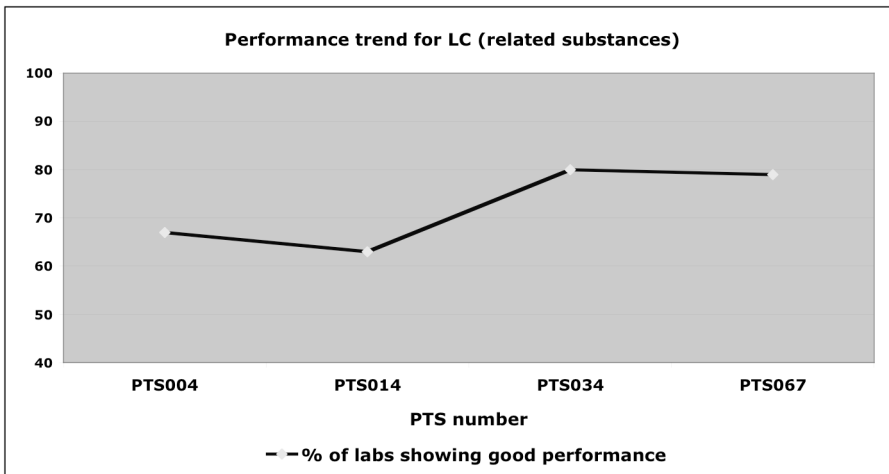
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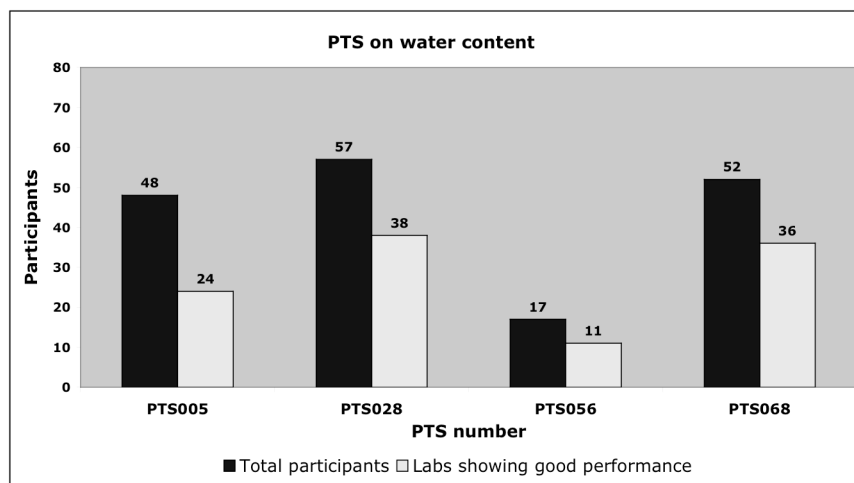
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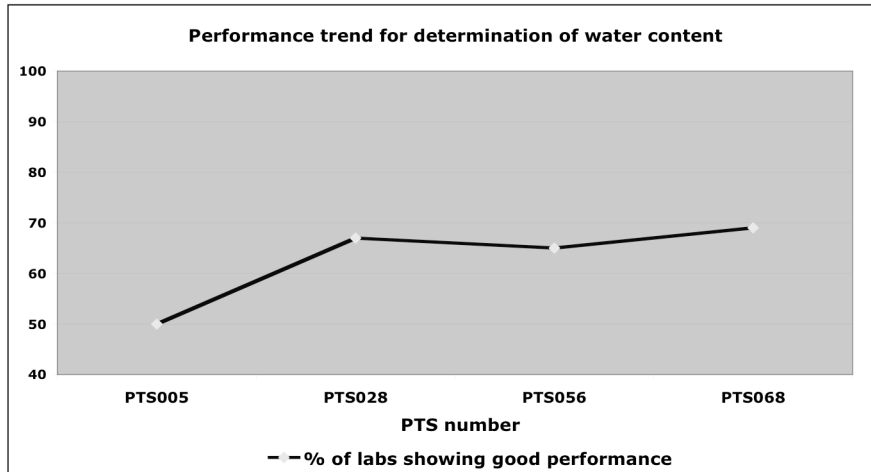
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General conclusion

- OMCLs and non-OMCL laboratories show increasing interest to participate in PTS studies
- Participation in PTS scheme helps laboratories to evaluate and improve their performance and to detect weak points in their quality system

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PROFICIENCY TESTING STUDIES FOR NAT ASSAYS. AN IMPORTANT TOOL FOR ASSURING THE QUALITY

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DEFINITION

“Proficiency testing is the use of interlaboratory comparison for determination of the performance of individual laboratories for specific tests or measurements and for monitoring laboratories continuing performance.”

(ISO/IEC Guide 43-1:1996)



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PROFICIENCY STUDIES (PTS)

- ✓ Means of assessing the ability of labs to competently perform specific tests ad/or measurements
- ✓ Supplement a laboratory's own internal quality assurance procedures
- ✓ Provide labs with a basis for continuous improvement
- ✓ Comparability of labs performance



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NUCLEIC AMPLIFICATION TECHNIQUES (NAT)

- Complex methods comprising sample preparation, amplification and detection
- Very sensitive methods
- A single nucleic acid molecule may be amplified a million times
- High sensitivity can result in false positive results
- Small variations in assay runs can result in false negative results

Sensitivity and specificity of NAT can vary
between laboratories



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HCV NAT PTS

(1)

Rationale

- ✓ Plasma pools are re-tested for HCV RNA by OMCLs as part of the Official Batch Release of blood derivatives
- ✓ Mutual confidence among OMCLs on NAT results is a prerequisite for mutual recognition
- ✓ Strong demand from OMCLs for Proficiency Studies on NAT



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EUROPEAN PHARMACOPOEIA



2.6.21

Nucleic Acid Amplification Techniques

“participation in external quality assessment is an important PCR quality assurance procedure for each laboratory and each operator”

EDQM organised such studies with the scientific advice of OMCLs



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METHOD OF WORK

EDQM enquiry / OMCL proposal

EDQM

- Feasibility check
- Proposal at Annual OMCL Meeting
- Appointment of Scientific Advisor
- Panel: procurement/processing
- Statistical evaluation of the results

Scientific Advisor

- Protocol design
- Choice of the preparations to be included in the panel
- Indication of the dilutions to be tested
- Preliminary laboratory testing
- Cooperation with EDQM

Report to participants



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HCV NAT PTS (2)

- Participation in PTS on voluntary basis
- Panel of 20 samples
 - ◆ Different genotypes
 - ◆ Serial dilutions (from 1 to 100 IU/ml)
 - ◆ High-titre samples
 - ◆ Negative samples
- Each lab is asked to perform its routine testing method and return results to EDQM
- Evaluation of results and preparation of a report
- A lab able to correctly detect all samples containing 100 IU/ml and all negative samples is considered “Satisfactory”



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HCV NAT PTS (3)

| Year | Study | No. of participants | Scientific advice |
|------|---------|---------------------|-------------------|
| 1999 | PTS 017 | 8 | ISS |
| | PTS 019 | 13 | |
| 2000 | PTS 029 | 11 | ISS |
| | PTS 031 | 12 | |
| 2001 | PTS 035 | 14 | PEI |
| | PTS 036 | 13 | |
| 2002 | PTS 040 | 11 | PEI |
| | PTS 042 | 15 | |
| 2003 | PTS 050 | 15 | SIPH |
| 2004 | PTS 054 | 20 | |



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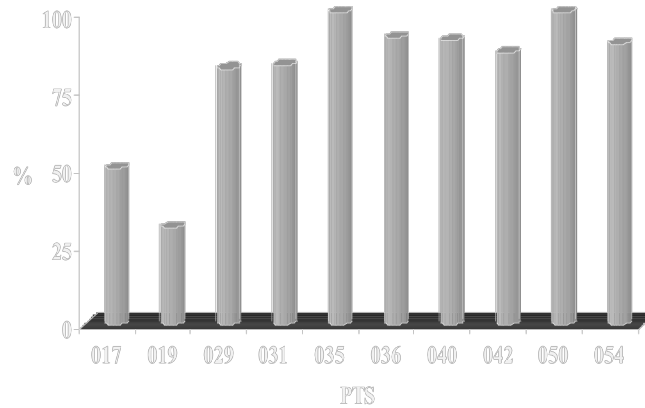
HCV NAT OVERALL RESULTS

| Study | Genotype | % positivity 100 IU/mL |
|---------|-----------------|---------------------------|
| PTS 017 | 1b - 3a | 92 - 78 |
| PTS 019 | 1b - 3a | 90 - 69 |
| PTS 029 | 1 - 3a | 88 - 91 |
| PTS 031 | 1 - 3a | 97 - 92 |
| PTS 035 | 1a - 1 | 100 |
| PTS 036 | 1/1b - 2b | 100 - 96 |
| PTS 040 | 1 | 97 |
| | 2 - 3a | 100 |
| PTS 042 | 1 | 93/96 |
| | 3a | 97/100 |
| PTS 050 | 1a/1b - 2b - 3a | 100 |
| PTS 054 | 1a - 1b - 2b | 95 - 100 - 100 |



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HCV NAT SATISFACTORY OMCLs



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B19 NAT PTS (1)

Rationale

- New Ph Eur requirements for plasma pools: testing for B19 DNA by NAT
 - ✓ Since January 2004 for plasma pools for the manufacture of anti-D Immunoglobulin
 - ✓ Since July 2004 for plasma pools for the manufacture of virus-inactivated plasma
- Maximum level acceptable: 10^4 IU/ml
- Plasma pools are re-tested for B19 DNA by OMCLs as part of the Official Batch Release of these products



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B19 NAT PTS

(2)

- 16 participants (OMCLs and Manufacturer)
- Panel consisting of 10 coded samples
 - 2 negative samples
 - 6 positive samples containing “standard” B19 DNA at 3 different concentrations (10^5 – 10^4 – 10^3 IU/ml)
 - 2 samples containing the A6 variant DNA at 2 different titres (10^6 and 10^2 IU/ml)



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B19 NAT PTS

(3)

Results

- Negative samples found to be below the threshold
- Performance quite “satisfactory” for B19 “standard” type
 - Samples containing 10^3 IU/ml were correctly identified as “pass”
 - One lab underestimated the “standard” B19 DNA at concentration of 10^5 IU/ml
- More than 50% of labs were not able to detect or quantify correctly A6 variant DNA at concentration of 10^6 IU/ml



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ISS ACTIVITY

- ✓ Participation in the PTS organised by the EDQM
- ✓ Organisation of EQA studies addressed to manufacturers of blood products to provide each participating laboratory with an external evaluation of their testing capability



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ISS EQAs

- EQA / 1 April 2000
September 2000 *Vox Sanguinis 2001; 81: 143-147*
- EQA / 2
- EQA / 3 September 2001 *Vox Sanguinis 2002; 82: 111-112*
- EQA / 4 December 2002 *Vox Sanguinis 2003; 85: 114-116*
- EQA / 5 December 2003 *Vox Sanguinis 2004; 87: 91-95*



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AIM OF THE STUDIES

- Assessing the proficiency of blood products manufacturer and blood centres in detecting by NAT the six major HCV genotypes (**EQA /4**)
- Assessing the proficiency of blood products manufacturer and blood centres in detecting by NAT the possible contamination of plasma with HCV, HIV and HBV (**EQA /5**)



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EQA/4 PANEL COMPOSITION

16 coded samples

- 12 positive samples, containing genotypes 1-6 with a nominal concentration of 100 IU/mL
 - HCV RNA ISS 0498 (genotype 1)
(*Vox Sang* 2000; 78: 217-224)
 - HCV genotypes 2-6 kindly provided by John Saldanha
(*Vox Sang* 2003; 84: 20-27)
- 4 negative replicates

NAT METHODS

Amplicor (19 labs), **TMA assay** (5 labs), **In-house** (7 labs)



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EQA/4: RESULTS

- ✓ This study represents the first one that included all the six major HCV genotypes
- ✓ Overall results can be considered satisfactory
 - Genotypes 1, 2 and 3 were correctly identified in 100% of the assays
 - Genotype 4 was correctly identified in 96.7% of the tests
 - Genotypes 5 and 6 were correctly identified in 98.3% of the assays



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EQA/5 PANEL COMPOSITION

HCV EQA/5: 10 coded samples

- 8 positive samples, containing genotypes 1-6 with a nominal concentration of 100 IU/mL
- 2 negative replicates

HIV EQA/1: 6 coded samples

- 2 replicates with a nominal concentration of 1000 IU/mL
- 2 replicates with a nominal concentration of 100 IU/mL
- 2 negative replicates

HBV EQA/1: 6 coded samples

- 2 replicates with a nominal concentration of 1000 IU/mL
- 2 replicates with a nominal concentration of 100 IU/mL
- 2 negative replicates



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PARTICIPANTS

46 laboratories participating in the EQA studies

- 9 blood product manufacturers
 - 2 from Germany
 - 2 from Italy
 - 1 from Argentina
 - 1 from Austria
 - 1 from Australia
 - 1 from Spain
 - 1 from Switzerland
- 1 diagnostic kit manufacturer
 - from U.S.A.
- 35 blood centres
 - 28 from Italy
 - 4 from Canada
 - 3 from UK
- 1 OMCL



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NAT METHODS

| Methods | HCV EQA/5 | HIV EQA/1 | HBV EQA/1 |
|--------------------------|--------------|--------------|--------------|
| Cobas Ampliscreen | 13 | 13 | 5 |
| HCV Cobas Amplicor v2.0 | 7 | | |
| HCV Amplicor v2.0 | 2 | | |
| Procleix HIV-1/HCV Assay | 16 | 16 | |
| Procleix Ultrio Assay | 1 | 1 | 3 |
| Other kits | | 1 | 1 |
| In-house | 7 | 4 | 7 |
| TOTAL | 46 | 35 | 16 |



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EQA/5: RESULTS

- ✓ **HCV EQA/5** \implies Improved proficiency of participants as compared to the EQA/4: 95.6% of participants detected all 6 genotypes at a concentration of 100 IU/mL
- \implies
- ✓ **HIV EQA/1** A concentration of 200 IU/mL would be advisable as the minimal sensitivity
- \implies
- ✓ **HBV EQA/1** A concentration lower than 100 IU/mL could represent the appropriate minimal requirement



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CONCLUSIONS

- Proficiency studies are important tools for monitoring the quality of laboratories
 - ✓ Provide labs with an objective means of assessing and documenting the reliability of the data
- PTS can result in a significant benefit for laboratories
 - ✓ Allow participants to become aware of unsuspected errors or problems



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