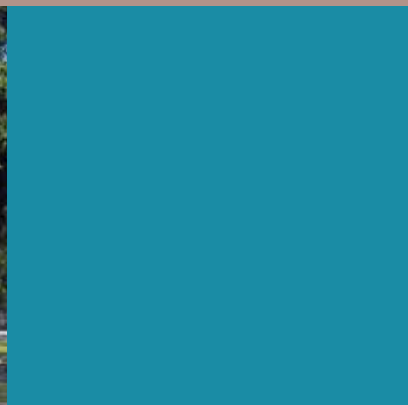


Public health, medicines, Europe

# The EDQM turns 50: to your very good health!





## **Dr Jean-Louis Robert**

### **Chair of the European Pharmacopoeia Commission, since 2013**

1976: PhD in Chemistry, University of Basel

1977: scientific collaborator, Pharmacy Faculty, Swiss Federal Institute of Technology in Zurich

1978: National Health Laboratory (LNS), Luxembourg

Since 1983: Member Group of Experts on Organic Chemistry Synthetic Products, European Pharmacopoeia

Member "CHMP" and Chair Quality Working Party human and veterinary medicinal products, European Medicines Agency. Member of various ICH working groups and WHO pharmaceutical expert

Head Pharmaceutical Chemistry Department, LNS

Foreign corresponding member of the Académie Nationale de Pharmacie (France)

## THE EUROPEAN PHARMACOPOEIA

> **Benefiting  
all...**

"The **European Pharmacopoeia** is used during the life-cycle of a medicine: development, production and commercialisation.

It harmonises the quality standards for medicinal substances, which, in their original state or in the form of pharmaceutical preparations, are of **general interest and importance to the peoples of Europe**, thus contributing to the **safe use of medicines**.

It is **constantly evolving** either to respond rapidly to **new risks to public health** (e.g.: heparin crisis, new safety issues) or to respond to **technical and scientific development**.

...It is one of **Europe's success stories** in the past 50 years, contributing to a harmonised understanding of pharmaceutical quality and as a consequence **benefiting all of us whenever we take our medicines...**".



## **DI Dr Christa Wirthumer-Hoche**

**Head of the Austrian Medicines and Medical Devices Agency (AGES), Austria, since 2013**

1981: Dipl. Ing. Biochemistry, Technical University Vienna

1983: doctoral thesis at the Institute for Medical Physiology

Since 1994: member of different European Committees and Working Parties

1998: Head of the Licensing Division for Medicinal Products, Austrian Federal Ministry of Health

2006: Head of Unit for Marketing Authorisation and Lifecycle Management, Austrian Medicines Agency

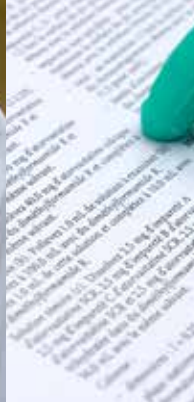
## THE EUROPEAN PHARMACOPOEIA

> An indispensable  
reference for  
the regulatory  
authorities

“According to our mission we see ourselves as a **national competent authority** being a partner in the European network and promoting **our values to be responsible, objective, competent and European.**”

The European Pharmacopoeia serves as a **fundamental compendium of quality standards** for active substances and excipients; it is **appreciated world-wide.**

The **Certification procedure**, to which a high number of Austrian quality assessors contribute on a routine basis, can be considered as **one of the most outstanding work-sharing projects** in the fields of medicines, ensuring an **excellent quality of assessment** using resources efficiently and thus **making a major contribution to public health...**”.



## THE EUROPEAN PHARMACOPOEIA

> An indispensable reference for testing by manufacturers

The European Pharmacopoeia, with its collection of samples of reference materials (reference standards), is used every day on industrial production sites to check the quality of batches of medicines (raw materials and finished products).

Industrial companies are obliged to comply not only with European Pharmacopoeia standards but also with good manufacturing practices.





## **Dr Philippe Girard**

**Head of Division OMCL (Laboratory), Swissmedic Switzerland, since 2007**

2001: PhD in bioprocess development from the Swiss Federal Institute of Technology Lausanne

2001: co-founded ExcellGene

2005: head of galenical development for a pharmaceutical company

Since 2008: member of European Pharmacopoeia groups of experts, on "monoclonal antibodies" and "innovative medicines", also member of the Advisory Group of the General OMCL Network

## OFFICIAL MEDICINES CONTROL LABORATORIES

> Playing an  
essential role  
in surveillance

“Defining the quality requirements and **exchanging information** between laboratories is essential for the success of the surveillance and the control of medicinal products and their ingredients.

With the Pharmacopoeia, the **EDQM** provides the quality requirements and with the “OMCL” Network, it provides a platform to exchange information on methods and results.

Both make my life easier...”

*edqm*

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& HealthCare | & soins de santé

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## OFFICIAL MEDICINES CONTROL LABORATORIES

> A dynamic  
network  
serving citizens  
more than ever

The missions of the network now include **detection of falsified medicines**, **monitoring of stockpiled medicines**, testing of pharmaceutical preparations produced in community and hospital pharmacies and **quality control of active pharmaceutical ingredients** on the European market.

Each year the network tests about **600 marketed medicines**, grants **10 000 certificates for the official batch release of vaccines** for human and veterinary use and produces over **300 analytical reports on illegal and counterfeit (falsified) products**.



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## CERTIFICATION OF SUITABILITY TO THE EUROPEAN PHARMACOPEIA

> In the context  
of globalisation

The Certification of suitability procedure was created to **ensure the quality of different sources of pharmaceutical substances** in the context of globalisation, whilst respecting requirements for public health.

**Certification of suitability** involves assessment and verification of information provided by manufacturers on their manufacturing processes and of quality control tests performed on a production site. Certification indicates that the quality specifications of the European Pharmacopoeia suitably control the quality of this substance.

It also provides an **open window** on world production, which makes it possible to keep the **European Pharmacopoeia** constantly up to date.



## Ms Andrea Cseh Palos

**Head of the Chemical and Radiochemical Assessments Department,  
National Institute of Pharmacy (NIP), Hungary, since 2009**

1986: graduated in Chemistry, Eötvös Lorand University of Sciences, Budapest

1999: chemical-pharmaceutical assessor, National Institute of Pharmacy (NIP), Hungary

Since 2002: External assessor of the Certification procedure at EDQM

Since 2008: Member of the Technical Advisory Board for Certification

2012: Post-graduated as a Clinical Medicines Development Scientist

## CERTIFICATION OF SUITABILITY TO THE EUROPEAN PHARMAPOEIA

> Continues  
to illustrate  
exemplary  
collaboration

“Certificates are used to demonstrate the quality of the substances and are recognised by the 37 member states as well as other countries.

The procedure facilitates and simplifies the authorisation process for medicinal products, both for industries and for authorities.

Certificates are granted based on a centralised evaluation carried out at EDQM. This is also a good opportunity to work together with quality assessors from different medicines agencies and exchange experiences and opinions.”






## THE EDQM Council of Europe in brief

> In addition to activities related to the Technical Secretariat of the European Pharmacopoeia Commission, the Certification Procedure and the Network of Official Medicines Control Laboratories (OMCLs), the EDQM also works in the areas of:

- **blood transfusion;**
- **transplantation;**
- **pharmaceuticals and pharmaceutical care** (protection of patients in Europe against counterfeit medicines; legal classification of medicines, quality standards and pharmaceutical practices);
- **and consumer health protection** (standards for the safety and quality of cosmetics and food-contact materials).



[www.edqm.eu](http://www.edqm.eu)

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The EDQM would like to thank all of those who have contributed to this exhibition.

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