

PERSONAL INFORMATION

Jean-Louis Robert

WORK EXPERIENCE

1977–1978

Scientific collaborator

E.Merck, pharmaceutical company (Germany)

November 1978–March 2015

Head of Unit

Laboratoire National de Santé, Département des Laboratoires Officiels de Contrôle (Luxembourg)

Official Medicines Control Laboratory (Service de Chimie Pharmaceutique)

Analytical control of medicines; scientific evaluation of chemical pharmaceutical dossiers for marketing applications

1983–June 2016

Expert and Chair

European Pharmacopoeia (France)

Pharmacopoeial Standardization

Expert (Group 10B) till March 2015 and Ph.Eur. Commission member (since 1995)

Chair Ph. Eur. Commission since June 2013 - June 2016

Elaboration of pharmacopoeial monographs till March 2015

1994–March 2015

Member representing the unit

European Network of Official Medicines Control Laboratory (France)

Quality control of medicines

Participation at laboratory activities, establishment of common procedures

1995–2004

Member of the Committee for Proprietary Medicinal products (CPMP)

European Medicines Agency (EMA) (United Kingdom)

Scientific Committee for Marketing Authorization

Expert chemical/pharmaceutical quality

2004–Present

Co-opted member of the Committee for Human Medicinal Products (CHMP)

European Medicines Agency (EMA) (United Kingdom)

Scientific Committee for Marketing Authorization

Expert chemical/pharmaceutical quality

1986–1994

Member

European Commission (Belgium)

CHMP/CVMP Quality Working Party

Harmonization of pharmaceutical quality requirements within applications for marketing authorizations.

1995–Present

Chairman of QWP since 1995

EMA/EMA (United Kingdom)

CHMP/CVMP Quality Working Party

Coordination and chairing the activities of the group

2004–Present **WHO Expert Advisory Panel International Pharmacopoeia and Pharmaceutical Preparations**

WHO, Geneva (Switzerland)

Quality Control

Preparation of Monographs for the International Pharmacopoeia

June 2017–Present **chair of CEP Steering Committee**

EDQM (France)

To chair the meeting of the Certification of Suitability of the European Pharmacopoeia (CEP)

EDUCATION AND TRAINING

1968–1972 **Diploma in chemistry (Diplom Chemiker)**

University of Basle (Switzerland)

Chemistry

1973–1976 **Ph.D.**

University of Basle, Institute for Organic Chemistry (Switzerland)

Bio-organic chemistry

Assistant for students lab work

February 1977–September 1977 **Scientific collaborator**

Institute of Pharmacy, Federal Institute of Technology (ETH) Zürich (Switzerland)

Analytical Chemistry

ADDITIONAL INFORMATION

Expertise

- Co-rapporteur in different centralized procedures and assessor for the chemical-pharmaceutical part of the dossier.
- Involvement within the International Conference on Harmonization (ICH): Validation of Analytical Procedures (Q2) as rapporteur, Common Technical Document-Quality as rapporteur, revision of the guidelines on impurities (Q3A and Q3B) as rapporteur, Pharmaceutical Development (Q8 and Q8R1), Pharmaceutical Quality System (Q10) and currently rapporteur for the Implementation Working Group ICH Q8, Q9, Q10. Lead of ICH Quality Informal Brainstorming Group (since 2012). EU topic leader for ICH Q12 (Lifecycle Management)
- 1997/2005: Chair of a working party at the Council of the EU during Luxembourg Presidency.
- Participation as speaker at different Conferences/Workshops in the pharmaceutical quality area organized among others by Drug Information Association (DIA), Parenteral Drug Association (PDA), International Society for Pharmaceutical Engineering (ISPE).
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Publications

Projects

Memberships

- Chair of the Luxembourg Ethical Committee for clinical research (Comité National d'Ethique en Recherche).
- Member of Luxembourg Anti Doping Agency (Agence Luxembourgeoise de la Lutte contre le Dopage)..
- Membre correspondant étranger "Académie Nationale de Pharmacie", France

Other Relevant Information

Mother tongue: Luxemburgish, French

Other languages: English (very good), German (very good)