

**“REGULATORY SUBMISSION PROCEDURES IN EU - APIs & DRUG PRODUCTS:
Special focus on GMP, European Pharmacopoeia
Requirements and the Certification Procedure”**

DATE : 13 - 14 November 2008
VENUE : Hotel Taj Gateway,
PLACE : Bangalore, India



WHO SHOULD ATTEND ?

- Senior Management
- Regulatory Affairs
- GMP Compliance
- Quality Assurance
- Product Development
- Manufacturing
- Consultants




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Contact Poonam Gandhi (0) 9999 182 087 OR (0129) 4037 457**

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SPEAKER PROFILE:

DR. CLAUDE COUNE was born in Belgium in 1950. He studied Pharmacy at the University of Liege, Belgium and became a Pharmacist in 1973 and in 1981, obtained his Ph.D. in Pharmacy. From 1974 to 1982, he was the Assistant Professor at the University of Liege. From 1982 to date, he has been working with the Technical Secretariat of the European Pharmacopoeia, first as the Secretary of several groups of Experts (Organic Chemistry and General Methods of Analysis) and presently, as Head of the Publications & Multimedia Department of the European Directorate for the Quality of Medicines & HealthCare (EDQM).

DR. ANDREW MCMATH graduated in Pharmacy and is a member of the Royal Pharmaceutical Society of Great Britain since 1987. He has experience in Hospital and Retail Pharmacy. He studied for a Diplôme d'Etudes Approfondies and then obtained his Ph.D. (Synthetic Organic Chemistry) in 1997 from the Faculty of Pharmacy, Université Paris V. He joined the French Medicines Agency as a Pharmaceutical Assessor the same year. Since 1999, he is a Scientific Officer in the Certification of Substances Division, European Directorate for the Quality of Medicines & HealthCare (EDQM).

DR. PASCALE POUKENS-REHWART studied Pharmacy at the University of Liège, Belgium. She obtained a Ph.D. in Pharmacognosy from the same University in 1994, where she worked as Research Assistant (1988-1994). From 1997 to 2000, she was Chemical - Pharmaceutical Assessor at the Belgian Health Authorities and was in charge of the Evaluation of the Quality part of the Dossiers for Marketing Authorisation Applications. Then, she joined the EDQM (European Directorate for the Quality of Medicines & HealthCare), where she has been working as Scientific Officer in the Certification Unit. Since 2001, she has also been working for the Division dealing with Development of Monographs and General Chapter where she is in charge of one of the two Phytochemical Groups of Experts.

MR. VIJAY KSHIRSAGAR is a hard core Quality Assurance professional with more than 30 years of rich and well-diversified experience in highly reputed multinational and national pharmaceutical companies. He is currently working for Unichem Laboratories Limited, Mumbai, India as Executive Vice President for Corporate Quality Assurance and Regulatory Affairs. He has earlier worked for Ranbaxy Laboratories Limited as Director - Quality Assurance (Pharma). Prior to this, he has worked for companies like Sun Pharma, Tata/Merind, IPCA, German Remedies, Lupin and Duphar Interfran. Mr. Kshirsagar's core exposure has been in the area of QA/QC/Regulatory/Analytical Development and Microbiology. Mr. Kshirsagar has the vast experience of successfully facing several Regulatory Audits including US FDA, MHRA, MCC, ANVISA, WHO - Geneva, etc. both for formulations and API. He has also successfully represented the company in international courts (US/UK) on Intellectual Property Related matters. Mr. Kshirsagar has been a frequent trainer in number of international and national forums having spoken on wide range of topics like GMP, GLP, Method Validations, Cleaning Validation, Microbiological Validations, Stability, Aseptic working, etc. He has graduated in Microbiology/Chemistry and is a Post - Graduate in Organo-Analytical Chemistry by Research from Mumbai University. His research papers are published in reputed journals.

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SCIENTIFIC PROGRAM DETAILS DAY-1 November 13, 2008 (Thursday)

0900 - 0930 hrs	Registration to the Seminar
0930 - 1100 hrs	SESSION - 1 {Vijay Kshirsagar} Salient aspects of compliance to EU GMP for API manufacturing
1100 - 1115 hrs	COFFEE BREAK
1115 - 1245 hrs	SESSION - 2 {Dr. Claude Coune} Missions of the EDQM: from its first mission, the elaboration of the European Pharmacopoeia, to the latest HealthCare activities <i>Introducing the EDQM Its origins</i> <i>Merging of Pharmacopoeias in Europe</i> <i>Organisation of the European Pharmacopoeia. How it works?</i> <i>Observer status, what it means?</i> EDQM Requirements of granting observer status to IP <i>OMCLs and HealthCare activities</i> QUESTION & ANSWER SESSION
1245 - 1345 hrs	LUNCH BREAK
1345 - 1500 hrs	SESSION - 3 {Dr. Claude Coune} How to use a European Monograph? <i>General and specific monographs: understanding the logic behind them</i> <i>Specific issues such as test methods for impurities and polymorphism</i> <i>Addressing the issues related to polymorphism</i> <i>Knowledge Database: easy access to information on monographs</i> QUESTION & ANSWER SESSION
1500 - 1515 hrs	COFFEE BREAK
1515 - 1630 hrs	SESSION - 4 {Dr. Claude Coune} Reference Standards in the European Pharmacopoeia How are Reference Standards created? How are Impurities listed? EDQM expectations regarding characterisation of impurities Impurity Standards Reference Standards Database QUESTION & ANSWER SESSION
1630 - 1730 hrs	EDQM ONE-TO-ONE SESSIONS : Certification (Dr. Andrew McMath & Dr. Pascale Poukens-Renwart) Monographs & Publications (Dr. Claude Coune).

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SCIENTIFIC PROGRAM DETAILS DAY-2 November 14, 2008 (Friday)

0930 - 1030 hrs	SESSION - 5 Certificate of Suitability Registration Procedure <i>What is a CEP?</i> <i>How it works? The Application Procedure electronic submissions</i> <i>eCTD submission of CEP</i> <i>Inspection programme</i> QUESTION & ANSWER SESSION	{Dr. Andrew McMath}
1030 - 1100 hrs	COFFEE BREAK	
1100 - 1215 hrs	SESSION - 6 Certificate of Suitability Review Procedure <i>Most Common Deficiencies Found in particular for impurities</i> <i>How to compile better dossiers</i> <i>How to write a Quality Overall Summary</i> QUESTION & ANSWER SESSION	{Dr. Pascale Poukens-Renwart}
1215 - 1315 hrs	LUNCH	
1315 - 1445 hrs	SESSION - 7 Granting of CEPs - Validity of Certificates <i>Procedure for Granting CEPs and Validity of CEPs</i> <i>Renewal/Revision Procedures of CEPs</i> <i>Effective management of post approval changes</i> QUESTION & ANSWER SESSION	{Dr. Pascale Poukens-Renwart}
1445 - 1515 hrs	COFFEE BREAK	
1515 - 1600 hrs	SESSION - 8 Common issues noticed during CEP/EDMF application review	{Vijay Kshirsagar}
1600 - 1630 hrs	Q & A SESSION	
1630 - 1700 hrs	CLOSURE	
1700 - 1800 hrs	EDQM ONE-TO-ONE SESSIONS : Certification (Dr. Andrew McMath & Dr. Pascale Poukens-Renwart) Monographs & Publications (Dr. Claude Coune).	

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