Annual Emerging Markets Workshop

Focus on Latin America:

Building quality submission and review processes and practices – Overcoming challenges and meeting expectations

23-24 January 2014

JW Marriott Hotel, Lima, Peru

PROGRAMME

CENTRE FOR INNOVATION IN REGULATORY SCIENCE

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Focus on Latin America: Building quality submission and review processes and practices – Overcoming challenges and meeting expectations

Background

In general, all agencies follow the same mission of ensuring that patients have timely access to safe, effective and high-quality new medicines. The technical requirements for the development of a new medicine are harmonised in the ICH countries, with the adoption or adaptation of these guidelines occurring in the non-ICH countries. In addition to the efforts to harmonise the technical guidelines for the development of new medicines, developing countries are proactively looking to align their activities regionally with overarching groups such ICH GCG, LSIF and APEC or ASEAN in Asia, EAC and SADC in Africa, and in Latin America, PAHO, PANDRH, and MERCOSUR.

Therefore, agencies understand that there may be opportunities to further the discussions regarding methodologies for cooperation in order to share information and activities such as safety data and the results of clinical site and manufacturing inspections, thereby using resources more effectively to assess novel medicines for their respective populations. The challenges for the agencies, however, centre on their variability in skill sets and processes.

As more agencies develop their processes and practices to take a science-based approach to regulation and risk-based decision making, a common understanding and regulatory language is being developed. This understanding includes clarity around what constitutes a quality review and the necessity to have good review practices (GRevP) embedded within the agencies, leading agencies to focus on ways to ensure that they are building quality into the dossier review process. Agencies in Asia Pacific and Latin America are actively developing and evolving their practices so that these can be in line with more widely followed good review practices.

The key question is what are the underpinning components that ensure good regulatory decision making and what are the regulatory science tools that can be built in and used to ensure a timely, high-quality, predictable and transparent process whilst ensuring an effective and efficient use of resources? Identifying these components has its challenges from the agency side as they look to ensure that this becomes more than just adherence to an esoteric guideline but also becomes part of the behaviours and practices of all staff members and that the knowledge, attitude and practices are all aligned.

It is the intent of this Workshop to discuss how agencies are building quality into their review process and what the challenges are to move from a guidance document to the use of good review practice in the daily workings of an agency and how this can help underpin good regulatory decisions, performance measurement, and quality. The themes of this Workshop carry forward a discussion begun in 2011 by CIRS amongst agencies at our Workshop in Kuala Lumpur, Malaysia and revisited this past January 2013 at our workshop in Beijing, China.

Workshop objectives

- **Identify current initiatives/approaches** being used by agencies building quality review systems and the role of good review practice in decision making
- **Discuss the challenges of** aligning knowledge of, attitude toward and practice of GRevP within agencies as they evolve their processes and procedures
- **Recommend approaches** to build quality and efficiency into agency review processes and practices
- **Understand the challenges** faced by the pharmaceutical industry in meeting diverse agency requirements and multiple requests for information during dossier reviews

Venue: The Workshop will take place at the JW Marriott Hotel in Lima, Peru commencing at 09:00 on 23rd January 2014 and finishing at 16:30 on 24th January 2014 (2-day Workshop).

Style and participation: Following the agreed practices for CIRS Workshops, attendance to the meeting will be by invitation to allow productive networking and discussions.

DAY 1: 23 JANUARY 2014

SESSION 1: GLOBAL FOCUS ON BUILDING QUALITY REVIEW PROCESS: THE ROLE OF GOOD REVIEW PRACTICES	
09:00	**Chairman's welcome and introduction** **Dr Murray Lumpkin**, Deputy Director, Regulatory Affairs, Global Regulatory Systems, Bill & Melinda Gates Foundation
09:05	**Country welcome and introduction by host agency** Representative from Ministry of Health, Peru
09:15	**Building a quality submission and review process: Why is this critical to the future evolution of agencies and regional regulatory alignment?** **PAHO/PANDRH experience: reference agencies, mutual recognition and information sharing** **Dr José Peña**, QF Regional Advisor, Medicines and Health Technologies, Pan-American Health Organisation (PAHO) / WHO
09:35	**Brazil experience** **Dr Renato Porto,** Director of Health Regulation, ANVISA, Brazil
09:55	**Discussion**
10.05	**Break**
10.35	**Good review practices: What are the challenges and benefits?** **Global consideration for developing GRevP** **Mike Ward**, Manager, International Programs Division, Health Canada
10:55	**Country perspective – Canadian experience** **Catherine Parker**, A/Senior Executive Director, Biologics and Genetics Therapies Directorate, Health Products and Food Branch, Health Canada
11.15	**Company perspective – How can GRevP enhance communication, transparency and clarity of submission and review expectations?** **Anthony Ventura**, Senor Director, Head, Latin America Region, Pfizer Inc, USA
11:35	**Discussion**
11:45	**Measuring good review practices: from guidance document to utilisation** **Neil McAuslane**, Scientific Director, CIRS
12.05	**A structured benefit-risk framework; more clarity and transparency?** **Prof Hans-Georg Eichler,** Senior Medical Officer, European Medicines Agency
12:25	**Discussion**
12:40	**Lunch**

SESSION 2: FOCUS ON LATIN AMERICA	
13:40	**Chairman's welcome and introduction** **Dr José Peña**, QF Regional Advisor, Medicines and Health Technologies, Pan-American Health Organisation (PAHO) / WHO
13:45 *14:10*	**Focus on Latin America: Adoption of good review practices – an assessment of where agencies excel and areas for improvement** **CIRS Survey Feedback** **Prisha Patel**, Manager, Emerging Markets Programme, CIRS **A Regional Viewpoint- the PRAIS initiative: PAHO** **Dr Analía Porrás,** Advisor, Medicines and Health Technologies, Pan-American Health Organisation (PAHO)/ WHO
14:30	**Discussion**
14:45	**Panel Discussion: Focus on Latin America: Submission requirements and review procedures: how are these converging?** **Question and answer period with panellists from invited agencies** **Dr.Helen Rosenbluth** (ANAMED, Chile), **Dr Pedro Yarasca**, (DIGEMID, Peru), **Beatriz Luna** (MSP, Uruguay), **Dr Analía Porrás** (PAHO)
16.00	**Introduction to roundtable discussions and break**
SESSION 3: ROUNDTABLE SESSIONS	
16.15	**The attendees will be organised into small roundtables to participate in facilitated discussions on key topics of interest to the participants Suggested topics include:** Roundtable 1: Regional alignment Chair: Emer Cooke; Rapporteur: Patrick O'Malley Roundtable 2: Elements of good-quality review and decision making Chair: Mike Ward; Rapporteur: Jill Jarusiewicz Roundtable 3: Facilitating the review process Chair: Prof Hans- Georg Eichler; Rapporteur: Aldo Topasio Roundtable 4: How to optimise stakeholder interactions? Chair: Dr. Murray Lumpkin; Rapporteur: Dorte Strobel Roundtable 5:Regulatory pathway for biosimilars Chair: Catherine Parker; Rapporteur: Birgitta Hedin
18.00	**End of roundtable discussions and end of day one**
19:00	**Reception**
19:30	**Dinner**

DAY 2: 24th January 2014

SESSION 3: ROUNDTABLE SESSIONS CONTINUE	
09.00	**Roundtable discussion group resumes**
09:45	**Roundtable discussions end and break**
10:15	**Chairman's Introduction** **Professor Sir Alasdair Breckenridge**, Former Chairman, MHRA, UK
10:20	**Feedback by roundtable session facilitators**
11:30	**Panel reflection from roundtable session – What are the next steps in Latin America in the implementation of GRevP? Viewpoints from:** ***Mike Ward**, Health Canada, **Dr Cristina Alonso Alija,** Bayer, **Lawrence Liberti,** CIRS and **Dr Pedro Yarasca,** DIGIMED*
12:30	**Lunch**
SESSION 4: FOCUS ON INTERNATIONAL INITIATIVES	
13:30	**Regulatory Co-operation: A nicety or a necessity?** **Dr Lembit Rägo**, Coordinator Quality Assurance and Safety: Medicines, World Health Organization
13:50	**Regulatory Cooperation – How does this work in practice and how do stakeholders ensure equity and quality of process?** **Dr. Mario Alanis Garza**, Advisor to the Commissioner**,** COFEPRIS
14:10	**Addressing the multinational complexity product submission in a non-converged environment: a pharmaceutical company viewpoint** **Dr Susan Forda,** Vice President, Global Regulatory Affairs, Eli Lilly, UK
14:30	**Discussion**
15:00	**Break**
15:30	**Regional Convergence Initiatives – A Tanzanian Perspective: What can be learnt from these activities?** **Hiiti B. Sillo,** Director General, Tanzania Food and Drugs Authority
15.45	**Panel reflection on regional convergence initiatives: What can be learnt from these activities?** **Transnational Agency consortia: Is this another route to the same place?** **Catherine Parker**, Acting Senior Executive Director, Biologics and Genetics Therapies Directorate, , Health Canada **Regional convergence from a company viewpoint** **Sharon Olmstead**, Global Head, Development and Regulatory Policy, Novartis, USA **European viewpoint** **Emer Cooke**, Head of International Affairs, European Medicines Agency **NGO viewpoint** **Dr Murray Lumpkin**, Deputy Directory, Regulatory Affairs, Global Regulatory Systems, Bill & Melinda Gates Foundation
16:20	**Discussion**
16:30	**Chairman's summary and close of Workshop**