

Official Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10

Presented by

ICH

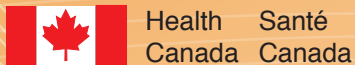
26-27 September, 2011

Government Conference Centre

2 Rideau Street (opposite Chateau Laurier)

Ottawa, ON K1N 8X5

Co-sponsored by



Interact with Over 100 Regulators

Dear Colleagues,

As we approach the official ICH Workshops on implementation of Q8, Q9 and Q10 in Ottawa, ON, I would like to remind you of the value of this opportunity.

The impact of ICH Q8, Q9, and Q10 is already being felt on the regulatory side of our business, and this impact will continue to grow. Don't miss the opportunity to interact with more than 100 regulators and learn from industry experts involved in the development of these guidelines. Contribute to a new era of refined pharmaceutical development by registering for this space-restricted event, the only such program presented by ICH in Canada.

These unique workshops will include a targeted case study followed by a full day of topic-specific Breakout Discussions. Participants will be divided into four teams and will rotate through each of four specialized Breakout Discussions covering Design Space, Control Strategy, Pharmaceutical Quality System, and Quality Risk Management. To maximize your experience, we encourage companies to send delegates to participate in each team.

There is limited space for delegates. Don't miss this rare opportunity to hear from, and engage with, such a broad group of regulatory and industry representatives. I look forward to seeing you at the workshop.

Jean-Louis Robert
Rapporteur for ICH Q-IWG
Chair, EMA-CHMP Quality Working Party

Workshop features

- How Q8, Q9 and Q10 can benefit pharmaceutical development, manufacturing, regulatory assessment, scale up to commercial operations and GMP-inspection
- A case study demonstrating opportunities for using the combination of Q8, Q9 and Q10
- Participate in discussions to develop solutions to implementation challenges
- Interact and network with more than 100 regulators and learn from industry experts (assessors and GMP-inspectors)
- Four specialized breakout discussions covering Design Space, Control Strategy, Pharmaceutical Quality System, and Quality Risk Management – participants will attend each discussion.

Faculty:

The workshop instructors will be regulators and industry experts serving the ICH Q-IWG and experts involved in development of the ICH Q8, Q9 and Q10 guidances.

Who Should Attend:

The workshops are open to all persons having interest in practical implementation of ICH Q8, Q9 and Q10, including regulators (assessors and GMP-inspectors) and industry (development, manufacturing, quality and regulatory affairs).

Participation by multiple representatives from each company is strongly recommended to gain maximum value from the four breakout discussions.

Feedback from the workshops will be used by the ICH Q-IWG to further facilitate harmonised implementation of ICH Q8, Q9 and Q10. The final workshop materials and outcomes will be presented to regulators and industry in the three ICH regions and will be made available to other regions as well. In addition, the workshop material is intended to be used for internal training purposes by industry and regulators.

In order to assure meaningful breakout discussions, attendance will be limited and early registration is encouraged.

Monday – 26 September

- 7:30 am Registration and Continental Breakfast
- 8:00 am **Welcome Remarks & Introduction**
Jean-Louis Robert, Rapporteur of ICH Q-IWG
Department of Quality Control of Medicine, Luxembourg
- 8:10 am **How ICH Q8, Q9, Q10 guidelines are working together throughout the product lifecycle.**
Moheb Nasr, FDA, CDER, USA, Q-IWG

Session A: How Q8 / Q9 / Q10 work in a life cycle approach

- 8:40 am **Case Study – Product Development**
Jean Wyvratt, Merck & Co., USA, Q-IWG
- 9:30 am **Case Study – Regulatory Assessment**
Elaine Morefield, FDA, CDER, USA, Q-IWG
- 10:15 am Coffee/Tea Break
- 10:45 am **Case Study – Implementation and PQS considerations**
Nigel Hamilton, Sanofi-Aventis, UK, Q-IWG
- 11:30 am **Case Study – Inspections at a manufacturing site**
Jacques Morénas, AFSSAPS, France, Q-IWG
- 12:15 pm **Panel discussion relating to today's presentations and planning for breakouts**
 Moderators: *Jean-Louis Robert, Department of Quality Control of Medicine, Luxembourg, Q-IWG and Moheb Nasr, FDA, CDER, USA, Q-IWG*
- 12:45 pm Lunch

Session B: Breakout Discussions

- 1:45 pm **Four teams (Blue, Red, Green, Brown)**
 – teams to stay in the same room – Facilitators will be rotating
- Track A: Design Space**
 Leaders: *Moheb Nasr, FDA, CDER, USA, Q-IWG and Georges France, Pfizer, UK, Q-IWG*
- Track B: Control Strategy**
 Leaders: *Bob Baum, Pfizer, USA and Jean-Louis Robert, Department of Quality Control of Medicine, Luxembourg*
- Track C: Pharmaceutical Quality System**
 Leaders: *Jacques Morénas, AFSSAPS, France, Q-IWG and Nigel Hamilton, Sanofi-Aventis, UK, Q-IWG*
- Track D: Quality Risk Management**
 Leaders: *Stephan Rönninger, F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG and Nicholas Cappuccino, Pharm IRS, USA, Q-IWG*

Four teams will go through all four topics – the teams will stay in the same room and the facilitators will move to different teams.

Monday pm	Design Space	Control Strategy	Pharmaceutical Quality System	Quality Risk Management
1:45 – 3:45	Team 1	Team 2	Team 3	Team 4
3:45 – 5:45	Team 2	Team 3	Team 4	Team 1

Tuesday - 27 September

Rotation continues

Tuesday am	Design Space	Control Strategy	Pharmaceutical Quality System	Quality Risk Management
8:00 – 10:00	Team 3	Team 4	Team 1	Team 2
10:00 – 12:00	Team 4	Team 1	Team 2	Team 3

12:00 pm – 1:30 pm Lunch

Moderator: *Stephan Rönninger, F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG*

Session C: Report from each workshop including addressing Q&A

1:30 pm Track A – Design Space

Moheb Nasr, FDA, CDER, USA, Q-IWG and Georges France, Pfizer, UK, Q-IWG

1:50 pm Track B – Control Strategy

Bob Baum, Pfizer, USA, Q-IWG and Jean-Louis Robert, Department of Quality Control of Medicine, Luxembourg, Q-IWG

2:10 pm Track C – Pharmaceutical Quality Systems

Jacques Morénas, AFSSAPS, France, Q-IWG and Nigel Hamilton, Sanofi-Aventis, UK, Q-IWG

2:30 pm Track D – Quality Risk Management

Stephan Rönninger, F. Hoffmann-La Roche, Ltd., Switzerland, Q-IWG and Nicholas Cappuccino, Pharm IRS, USA, Q-IWG

2:50 pm Coffee/ Tea Break

Moderator: *Jean-Louis Robert, Department of Quality Control of Medicine, Luxembourg, Q-IWG*

Session D: Panel Discussion Q & A

3:20 pm Open Q&A from floor

Jacques Morenas, AFSSAPS, France
Moheb Nasr, FDA, CDER, USA
Georges France, Pfizer, UK
Bob Baum, Pfizer, USA
Nicholas Cappuccino, Pharm IRS, USA

4:20 pm Workshop Conclusions and Next Steps

Jean-Louis Robert, Rapporteur of ICH Q-IWG
Department of Quality Control of Medicine, Luxembourg

4.30 pm End of Conference

REGISTER TODAY AT www.cspscanada.org

Rates:

	Early Bird (by Aug.15)	Regular fee
Members	\$850.00	\$1050.00
Non-members	\$1000.00	\$1200.00
Health Canada	\$250.00	\$300.00

