

## Sabina Hoekstra-van den Bosch

- NL Ministry of Health, Welfare and Sport  
Department of Pharmaceutical Affairs and  
Medical Technology
- EU Working Group  
on New and Emerging Technologies  
in Medical Devices
- Global Harmonisation Task Force  
Ad Hoc Working Group on  
Combination Products

## Chuck Hoiberg, Ph.D.

Vice Chair, ISPE International  
Board of Directors

## Scope of ISPE's Product Quality Lifecycle Implementation (PQLI)

- Work with industry and regulatory leaders worldwide to develop pragmatic and practical implementation of ICH guidances based on sound scientific, engineering and business principles
- Focus on 3 ICH Regions; consider others
- Emphasis on "how to" ICH Q-8-9-10
- Industry lead
- Not regulatory documents
  - but industry views on regulations may drive debate
- Outputs are technical processes to be made available in white papers, technical documents, and educational & training forums

ENGINEERING PHARMACEUTICAL INNOVATION



## PQLI Topic Areas & Team Leads

- **Criticality**
  - Tom Schultz - J & J
  - Roger Nosal – Pfizer
- **Control Strategy**
  - Bruce Davis – AZ
  - Line Lundsberg – NNE Pharmaplan
- **Design Space**
  - Jim Spavins, Pfizer
  - John Lepore – Merck
- **Legacy Products**
  - Chris Potter

ENGINEERING PHARMACEUTICAL INNOVATION





Richard Levy, Ph.D.  
Senior Vice President Scientific and  
Regulatory Affairs  
Parenteral Drug Association (PDA)



Joseph Lim, Ph.D.  
Pharmaceutical Assessor  
Medicines and Healthcare products  
Regulatory Agency (MHRA)



**U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

Rik Lostritto, Ph.D.

Director, Division of Pre-Marketing  
Assessment III & Manufacturing  
Science

Food and Drug Administration (FDA)

***Product Quality Research Institute (PQRI)  
and Quality By Design Projects***



Product Quality Research Institute

*Reggie Saraceno*  
Chair, Development Technical Committee

## Quality by Design

Two major initiatives are currently underway

- | Applying QbD to drug release/bioavailability
- | Lifecycle management of specifications in a QbD environment

## QbD for Drug Release

Goals:

- | Define a systematic approach to drug development through identification of potential CPPs and CQAs relevant to drug release
- | Define a process that will enable correlation of potential CQAs with bioavailability
- | Stimulate discussion among industry and regulators on the processes defined above, laying the groundwork for moving QbD for Drug Release forward

## Deliverables: Systematic Approach to Drug Development

- I A high-level decision tree that can be followed to determine potential CQAs relevant to drug release and their associated CPPs for a given manufacturing process
- I Examples of how the decision tree can be followed in two specific cases
  - BCS Class II compound in a wet granulated IR tablet
  - BCS Class I compound in a direct compression modified release tablet

## Deliverables: Clinical Relevance

- I Define the design of and criteria for clinical studies that can be used to evaluate the potential biological relevance of CQAs
  - Will include statistical guidance related to the number of subjects needed
- I Explore alternatives to human studies for evaluation of the relevance of CQAs to bioavailability



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Terrence Tougas, Ph.D., Chair  
International Pharmaceutical Aerosol  
Consortium on Regulation and Science  
(IPAC-RS)



## ***Our Mission***

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To enhance the quality and availability to patients of inhaled and intranasal drug products through scientifically driven advancements related to the development and regulation of these products



## ***Unique Challenges for Quality by Design of OINDPs***

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- Ø Supply Chain (container closure and device)
- Ø OINDP are complex combination products:
  - § Challenge: Interaction between formulation and device
  - § Opportunities: Device development side has experience in applying “QbD” approaches
- Ø Linking measurable product attributes to product/clinical performance to establish Quality
- Ø Communicating development knowledge to regulators