

Summary Day 1: Industry as Change Agent

- Ø Business and social environment is changing. QbD is part of this change. OINDP industry needs to be actively involved in this change
 - § Consider social and business responsibilities, e.g., access, affordability, sustainability
 - § Understand and work effectively within globalized environment
 - § Operate with lifecycle perspective
- Ø Industry must take the lead in addressing many of the challenges afforded by QbD implementation and in advancing ICH/QbD concepts. *These are opportunities!*

Summary Day 1: Risk and Knowledge Management

- Ø Need to share knowledge of product and process understanding within companies and with regulators
- Ø Submissions should be driven by knowledge of the product and its use, not just data.
- Ø Use risk and knowledge management to promote transparency, rational approaches, and information sharing in the drug lifecycle

Summary Day 1: The End User

- Ø Listen to what the patients want and need from a product. Keep it simple
- Ø Provide clear, simple, and graphical product use instructions
- Ø Consider patient advocacy groups as key stakeholders

Summary Day 1: Guidelines/Guidance and Standards

- Ø There is a need for further harmonization of guidelines, guidance, standards, etc for OINDP. The industry can help clarify what guidance/guidelines are needed for OINDP
- Ø Standards development afford a number of opportunities for industry, regulators, academia and other experts to develop consensus on areas of mutual interest