



**CONCLUSIONS FROM
INFORMAL DISCUSSION GROUP**

GMP

**GMP Workshop and
New proposal for the development of an ICH Guideline on GMP
related issues**

last update : 18 July 2003

Topic Adopted	Quality Systems for the 21 st Century
Current Status	Brainstorm Session July 16, 17, 18
Current Draft (version, date)	
Next Draft Expected	
Deadline for Comments on the Draft	
Date Step Expected	
Rapporteur	Ajaz Hussain and Gordon Munro
Last Meeting	
Next Meeting	

Status Report:

Agreed Vision: A harmonized pharmaceutical quality system applicable across the life cycle of the product emphasizing an integrated approach to risk management and science.

Action Required:

1. Confirm the EWG proposed in February on Pharmaceutical Development (P2) to incorporate elements of Risk and Quality By Design and ensure membership reflects product life cycle.

Next Steps: Concept paper to be developed by current CTD-Q group. Needs a statement on possible impact on how inspectors operate (no direct impact on inspection resources). Revised concept paper to be circulated by mid-September for discussion at October Steering Committee teleconference. Membership CTD-Q plus. 3 names from each of the ICH member organization and one name from each observer to John Berridge within the next week. Work to begin in Osaka.

2. Recommend EWG to better define the principles by which Risk Management is integrated into decisions regarding quality including GMP compliance both by the regulators and industry. This would include developing a framework of Risk Management that will lead to more consistent science based decision-making. It will include elements such as Risk Identification, Assessment, Mitigation, and Communication. These principles will be applicable in pharmaceutical development and manufacturing (across life cycle of the product). Level and intensity of regulatory oversight would be adjusted according to the level of risk. This EWG would progress in parallel with P2 giving input into P2 and receiving input from P2.

Report Form: GMP Workshop

Next Steps: Need a formal concept paper setting out the problem, proposed solution, composition of EWG, and likely timeline. Greg Guyer will lead development of concept paper. Needs at least one member from each ICH member organization. Welcome other input from organizations experienced in risk management. Need to work closely with P2 team.

3. Industry to produce a Quality Systems scoping document including GMP as a subset. This document will address areas of perceived differences in the three regions and make proposals for the future. This document is to be available for discussion by mid-October.

Next steps: Proceed with developing paper and circulating to ICH participants. Will be basis for decision on whether or not an ICH concept paper should be developed. Consider implications on inspectional resources. Joyce Ramsbotham will lead the development of this document.

4. Develop principles for Introduction of New Technology Challenges and Opportunities concept paper before Osaka.

Next steps: (not discussed at Steering Committee) Ajaz to proceed with developing white paper. No formal commitment yet for next steps.

5. Recommend a representative small team to develop prioritized proposals for any additional modular steps to support the vision in order to develop an Overall Plan for further discussion at Osaka.

Next steps: (not discussed at Steering Committee) Toby Massa will lead this effort.