GHTF STUDY GROUP MEETING

HILTON WASHINGTON DC NORTH
GAITHERSBURG, September 12-16, 2005

STUDY GROUP 3

Alain Prat Chairman SG3

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- **Purpose of the study group**

SG3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization.

Memorandum Of Understanding Between ISO/TC 210 And GHTF In The Field Of Quality Management

- ***Promote communication***
- ***Avoid duplication***

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- **Participants**

Mr. Alain Prat
Mr. Shigetaka Miura
Mr. Werner Schöenbüehler
Mrs. Kimberly Trautman
Mr. Egan Cobbold
Mr. Gunter Frey
Mr. Hideki Asai
Dr. Ken Nicol
Mr. Keith M. Smith BE
Mr John Gams
Dr. Victor Dorman-Smith
Mr. Kenneth F. Kopesky

Experts / links :

» *Mr Tony Chan*
» *Mr Harvey Rudolph*

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- **Past works**
  - **Guidance on Quality Systems for the Design & Manufacturing of Medical Devices**
  - **Design Control Guidance for Medical Device Manufacturers**

Now incorporated in ISO TR 14969:2004 in which GHTF SG#3 participated

- **Past works**

  - **Implementation of Risk Management Principles and Activities Within a Quality Management System** (SG3/N15R8/2005)

  - **Quality Management Systems - Process Validation Guidance** (SG3/N99-10 - Edition 2)

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- **Present works**
  - **SG3 Participation on guidance on Regulatory Auditing Strategy – Implementation of risk management**
    - **Joints working group with SG4**
  - **New work Item Proposal Guidance on supplier and outsourced processes**
    - **To present an update for next SC for approval**
  - **Technical cooperation for quality management aspects with other study groups**

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- **Future works**

- Review the public comments received on the Regulatory Auditing strategy in conjunction with SG4

- Develop the guidance on supplier and outsourcing as approved by steering committee

- Develop other collaborations with other study group (SG1 regarding quality management system aspects, SG5 on risk management aspects)

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- **Some issues on suppliers and outsourced processes**
  - **Various regulatory schemes**
  - **Concept of manufacturer different from one authority to another**
  - **Ambiguity of regulatory requirements**
  - **Industry inconsistency in the application of the quality management system**
  - **Clarification of the roles and responsibilities**

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- **Proposed timetable for this guidance**
  - **November 2005 - London - Approval of updated NWIP by SC**
  - **September 2005 to March 2006 - SG3 perform literature review/gather information**
  - **March 2006 - Paris (AFSSAPS) - SG3 meeting**
  - **June 2006 – Lubeck - SG3 meeting**
  - **November 2006 - Japan – SG3 meeting**
  - **March 2007 - Proposed Document ready for SC**

- **Short experience as a ‘’New chairman’’**
  - **Fruitful experience within the group**
  - **Joint group meeting are very important**
    - **Technical cooperation in a certain domain**
    - **Exchange of experience**
    - **To avoid inconsistency among SGs**
  - **Other possibilities : technical consultation, dispatch a SG member for a period of time,…**

- **One Proposition : a GHTF Glossary**

- Collection of all definitions present in GHTF papers

- Review by a trans-horizontal group

- Composed of representative members of each study group and steering committee

- To achieve consensus about horizontal definitions

CONCLUSION

No result is achieved without effort or pain

BUT

That's part of the excitement of life