



U.S. FDA

Implementation of GHTF Guidance Documents

David W. Feigal, M.D., M.P.H.

Director, Center for Devices and
Radiological Health, FDA





Steps for US Implementation



Assessment of Consistency with US Law

Law (Statute)

- Does the GHTF Document require a change in the US Law ?
 -  Contradicts current statutes
 -  Reaches beyond current statute

Regulation

(binding requirements to meet the Law)

- Does the GHTF Document require a change in the way Regulations implement the Law ?

Guidance





(non-binding advice on a regulation or Law)

- Does the GHTF Document require modification or development of new guidance?

Steps for US Implementation



When a GHTF Document is being finalized ...

-  Publication of the Draft GHTF document for comment (*after review by FDA Counsel*)
-  Publication of Final GHTF document as Guidance
-  Development of needed new or modified regulations
 - Direct Final Rules (for noncontroversial technical changes in existing regulations)
 - Proposed Rules (new regulations)
 -  Notice and Comments
 - Final Rules
 - Guidance on the New Regulation



Study Group Implementation



Final GHTF Documents		Intended Audience (Regulators or Industry)	Status of FDA Implementation			
			Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
Study Group	Document					
1	N20R5	Both	No	Parallel System	Yes	No
	N9R6	Both	Yes		No	No
	N12R10	Both	Yes		No	No
2	N7R1	Both	Yes		No	No
	N8R4	Both	Yes		No	No
	N21R8	Both	No	Yes	Yes	No
3	N99-8	Both	Yes		No	No
	N99-9	Both	Yes		No	No
	N99-10	Both	No	Yes	No	No
4	4(99) 28	Both	No	Yes	No	No
	4(99) 14	Both	Yes		No	No
	4(00) 3	Regulators	No	Yes	No	No
	N26R1	Regulators	No	Yes	No	No



Study Group 1 Implementation



Final GHTF Documents Study Group 1 – “Premarket”	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG1-N020R5: Essential Principles of Safety & Performance of Medical Devices	Regu- lators & Industry	No	Parallel system achieves same objectives	Yes	No

- Provides guidance on the minimum elements that must be considered to assure safety and performance of devices
- FDA has parallel review process that achieves the objectives in the guidance



Study Group 2 Implementation



Final GHTF Documents Study Group 2 – Vigilance	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG2-N21R8: Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative	Regulators & Industry	No	Yes	Yes	No
<ul style="list-style-type: none"> • Provides guidance for deciding what events to report • FDA has implemented the most of this guidance 					

Study Group 3 Implementation



Final GHTF Documents Study Group 3	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG3-N99-10: Process Validation Guidance for Medical Device Manufacturers	Regulators & Industry	No	Yes – Utilizing it in training and encouraging industry to use	No	No

- FDA is taking steps to recognize this guidance through the Good Guidance Practices procedure which will involve announcing document availability through the Federal Register and seeking comments
- FDA is referring to this guidance in training within FDA and encouraging industry to use the guidance



Study Group 4 Implementation



Final GHTF Documents Study Group 4	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG 4(99) 28: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements	Regu- lators and Industry	No	Yes	No	No

- Describes how to manage an audit program, general qualifications and training for auditors, the role of auditors and manufacturers during the audit, what are serious deficiencies, content and distribution of audit report
- FDA has implemented most aspects of this guidance by incorporating changes in existing FDA documents such as the Investigators Operations Manual, Compliance Programs, and other documents
- FDA is committed to implementing remainder of guidance where regulatory requirements and policies allow.

Study Group 4 Implementation



Final GHTF Documents Study Group 4	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG4(00) 3: Training Requirements for Auditors	Regulators	No	Yes	No	No

- Describes training requirements for:
 - Training auditors to audit medical device manufacturers' quality systems
 - Updating auditors on new requirements and policies
 - Auditor's own professional development
- FDA's Office of Regulatory Affairs, Div. Of Human Resource Development, carries out most of these activities.



Study Group 4 Implementation



Final GHTF Documents Study Group 4	Intended Audience (Regulators or Industry)	Status of FDA Implementation			
		Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
SG4-N26R1:2001: Observed Audits of Conformity Assessment Bodies	Regu- lators	No	Yes	No	No

- Provides guidance when one conformity assessment body observes audits conducted by another conformity assessment body to build confidence in their ability to conduct meaningful audits prior to the exchange of and reliance on audit reports.
- FDA is using a modified version of the procedure described in this guidance in conducting joint audits under the Mutual Recognition Agreement (MRA) with the European Commission (EC)



Study Group Implementation




Final GHTF Documents		Intended Audience (Regulators or Industry)	Status of FDA Implementation			
			Fully Implemented	Partially Implemented	New/Revised Regulation Needed	Legislative Change Needed
Study Group	Document					
1	N20R5	Both	No	Parallel System	Yes	No
	N9R6	Both	Yes		No	No
	N12R10	Both	Yes		No	No
2	N7R1	Both	Yes		No	No
	N8R4	Both	Yes		No	No
	N21R8	Both	No	Yes	Yes	No
3	N99-8	Both	Yes		No	No
	N99-9	Both	Yes		No	No
	N99-10	Both	No	Yes	No	No
4	4(99) 28	Both	No	Yes	No	No
	4(99) 14	Both	Yes		No	No
	4(00) 3	Regulators	No	Yes	No	No
	N26R1	Regulators	No	Yes	No	No




Steps for US Implementation




Finishing the Process

 Publicly Highlighting GHTF Documents

- Workshops
- Speeches
- Advisory Panel Sessions

 Training FDA Staff

 Identification and recognition of the value added by Harmonization

