EUROPE AND GHTF GUIDANCE

It is Europe's intention to integrate GHTF guidance into the European legal framework to as full an extent as possible.

The main elements of the European legal framework that can be used to achieve this are the European Medical Devices Directives themselves and the European Commission's Medical Device Guidance Documents, the so called 'MEDDEVs'.

The Medical Devices Directives and the MEDDEVs are broadly in line with GHTF. Of course there may be minutiae that differ, but to focus on these is to miss the point of GHTF and 'harmonization' to GHTF. In Europe we do not see harmonization to mean simply cutting and pasting, we see harmonization as alignment. This alignment may differ in the detail but the aim is to be coherent with GHTF guidance in the main. It is important to remember that these differences are very often not globally inconsistent with GHTF but merely tailor the GHTF guidance to fit the European Directives and the MEDDEVs as implemented by national authorities.

Europe will build on this initial analysis of harmonization to GHTF guidance and, where there is scope and opportunity to do so, is committed to even closer alignment.

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SG	PD & FD Guidance #s	PD & FD Guidances	Harmonized or Adopted Elements of Guidance	Obstacles or Disagreements to Harmonization **OR** Projected Timeline for Harmonization
1	**SG1(PD)N44:2006**	Role of Standards	All major elements are fully adopted. Note: SG1(PD)N44 is published on the GHTF website for public comments until March 15, 2007 and may be amended during the next SG1 meeting.	
5	SG5(PD)N2R7:2006	Clinical Evaluation		Europe intends to replace the 1st part of the MEDEV on clinical evaluation by the GHTF document]
5	SG5(PD)N1R7:2006	Clinical Evidence – Key Definitions and Concepts		Europe intends to replace the 1st part of the MEDEV on clinical evaluation by the GHTF document]
4	SG4(PD)N33R13:2006	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports	Overall content useful but still under discussion	To be discussed
2	SG2(PD)/N87R7:2006	An XML Schema for the electronic transfer of adverse event	To be developed or searching experiences during a pilot phase	

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		data between manufacturers, authorized representatives and National Competent Authorities (Based on GHTF SG2N32v5.2)		
1	**SG1/N41R9:2005**	Essential Principles of Safety & Performance of Medical Devices	Adopted in the form 'Essential Requirtements' in Annex 1 of Directives 90/385/EEC, 93/42/EEC and 98/79/EC. There are only slight differences, e.g. - requirements for self-testing or self-administration devices acc. to point 5.15 of SG1/N41 are only included in Annex I of Directive 98/79/EC.	
1	**SG1/N29R16:2005**	Information Document Concerning the Definition of the Term "Medical Device"	The definition of "medical device" in SG1/N29 has a different wording in comparison to the European directives. However, this results only in few differences concerning the products covered by the definition, e.g. - devices for diagnosis, monitoring, treatment, alleviation of or compensation for a handicap are not part of the GHTF definition.	

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1	**SG1/N43:2005**	Labelling for Medical Devices	Adopted as part of the labeling requirements in Annex 1 of Directives 90/385/EEC, 93/42/EEC and 98/79/EC. There are only slight differences, e.g. - the points w) to dd) of SG1/N43 apply for users, patients and medical staff whereas the equivalent points 13.6 k) to p) of Annex I of Directive 93/42/EEC apply for medical staff only. - Specifically for IVDs, SG1/N43 only contains the additional points ee) to oo), which do not cover all the specific labeling requirements contained in Annex I, point 8 of Directive 98/79/EC. - SG1/N43 states in the general principles: *Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request.* This aspect is not fully adopted. General view: IFU are part of the whole device which is only safe and effective if it used in accordance with the IFU. With the revised directive additional labelling requirements for specific devices were introduced (Phthalates)	

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1	**SG1/N9R6**	Labelling for Medical Devices	SG1/N9 is superseded by SG1/N43.	
1	**SG1/N40:2006**	Principles of Conformity Assessment for Medical Devices	Adopted in Art. 9 of Directive 90/385/EEC and Art. 11 of Directive 93/42/EEC. There are only slight differences, e.g. - type examination is mentioned in SG1/N40 only as an alternative allowed in some country or regional regulations, - there is a QMS required for class I device manufacturers. Note: IVDs will be covered by a separate SG1 document.	
1	**SG1/N15:2006**	Principles of Medical Devices Classification	Adopted in Annex IX of Directive 93/42/EEC (the European classes I to III correspond to the GHTF classes A to D). The main differences are: - Active implantable medical devices are class D acc. to rule 8 of SG1/N15, in Europe they are not 'classified' as class D but are the subject of a specific directive, 90/358/EEC, which, de facto, treats them as class D devices. - acc. to rule 15 of SG1/N15 all devices intended specifically to be used for	

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			sterilizing medical devices, or disinfecting as the end point of processing are in class C, unless the are intended for disinfecting medical devices prior to end point sterilization or higher level disinfection, in which case they are in class B, - there is no special rule in SG1/N15 classifying devices for recording X-ray images. Therefore they are only class A whereas acc. to Directive 93/42/EEC they are class IIa. Note: IVDs will be covered by a separate SG1 document.	At the adoption of this document by the SC, SG 1 were asked to look at this point again in the future.
1	**SG1/N12R10**	Role of Standards in the Assessment of Medical Devices	SG1/N12 will be superseded by SG1/N44.	
3	SG3/N15R8:2005	Implementation of Risk Management Principles and Activities Within a Quality Management System		
3	SG3/N99-10 (Edition	Quality		

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	2)	Management Systems – Process Validation Guidance		
4	SG4(99) 14	Audit Language Requirements (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements – Supplement 1)	Content accepted and common understanding	Document should be included in "General Requirements" document (already decided in SG 4), compare SG4 / N 69 – 2 Existing Supplements (Final Documents) Supplement 1 "Audit language requirements SG4 (99) 14", shall be integrated into the revised document.
4	SG4(99)28	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General	Document adopted as European MEDDEV 2.5/2 rev 3[1]	Document outdated but revision already in progress, compare SG4 / N 69 – 2

[1] http://ec.europa.eu/enterprise/medical_devices/meddev/index.htm

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		Requirements		
4	SG4/N30R20:2006	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy	Very important document, use (with some modifications/adaptations to the specifics of the European system) is recommended for Notified Bodies	To be discussed
4	SG4-N(99)24R3	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General Requirements – Supplement No. 4 – Compilation of Audit Documentation (Clause 5.7)	Content accepted and common understanding	Document should be included in "General Requirements" document (already decided in SG 4), compare SG4 / N 69 – 2 Supplement 4 "Compilation of Audit Documentation SG4/N(99)24R3:2002 shall be integrated into the revised document.
4	SG4-N26R1:2001	Guidelines for Regulatory	Content adopted only in parts; issue relevant especially for MRAs;	Document is helpful and practicable/applicable only in parts; issue will be addressed in the revised

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		Auditing of Quality Systems of Medical Device Manufacturers: General Requirements Supplement No. 6 Observed Audits of Conformity Assessment Bodies	compare SG4 / N 69 – 2 - Supplement No. 6 "Observed Audits of Conformity Assessment Bodies" SG4/N26R1:2001 shall not be integrated and it is proposed to the Steering Committee to archive this document and to remove it from the list of final documents.	"General requirements" document
4	SG4 (00) 3	Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements – Supplement 2)		Document should be included in "General Requirements" document (already decided in SG 4), compare SG4 / N 69 – 2 Supplement 3 "Training requirements for auditors" SG4 (00) 3 shall be integrated into the revised document.
2	SG2/N21R8	Adverse Event Reporting Guidance for	With regard to SG 2 papers: All major aspects are implemented into a MEDDEV ..	Due to the fact that the vigilance system is described in a non-legal binding guidance paper, small deviations (small differences in time frames or

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		the Medical Device Manufacturer or its Authorized Representative	Minor differences exist, like - European Vigilance system also cover reports from users, whereas the GHTF is only dealing with reports from manufacturers. - small differences in definition of incident/near incident - There are some GHTF exemption rules which are not transposed into the European System since the underlying "incidents" are not considered as incidents according to the European regulation. - At the European level the exchange of information concerning vigilance reporting is higher than for the GHTF NCAR system. (Meaning: Also reports which don't fulfill the criteria of NCAR are distributed between European CAs.	templates etc.) at the national level could occur. Due to the revised European Medical Devices Directives there is the possibility to eliminate these small national deviations
2	SG2/N38R3	Application Requirements for Participation in the GHTF National Competent Authority Report Exchange	See above	

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		Program		
2	SG2/N16R5	Charge & Mission Statement	See above	
2	SG2/N6R3	Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan	See above	
2	SG2/N9R11	Global Medical Device Competent Authority Report	See above	
2	SG2/N8R4	Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices	See above	
2	SG2-N36R7	Manufacturer's Trend Reporting of	See above	

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		Adverse Events		
2	SG2-N54R8:2006	Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices	See above	
2	SG2/N57R8:2006	Medical Devices Post Market Surveillance: Content of Field Safety Notices	See above	
2	SG2-N20R10	Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria	See above	
2	SG2/N79R8:2006	Medical Devices: Post	See above	

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		Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form		
2	SG2/N31R8	Medical Device Postmarket Vigilance and Surveillance: Proposal for Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Representative	See above	
2	SG2-N33R11	Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports	See above	
2	SG2/N32R5	Medical Device	See above	

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		Postmarket Vigilance and Surveillance: Universal Data Set for Manufacturer Adverse Event Reports		
2	SG2/N47R4:2005	Review of Current Requirements on Postmarket Surveillance	See above	
2	SG2/N68R3:2005	Summary of Current Requirements for Where to Send Adverse Event Reports	See above	

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