



**AdvaMed**

Advanced Medical Technology Association

# Guidance Development and Prioritization

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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- Background
- Guidance development process
- Guidance document priorities
- Updating current guidance documents
- Use of guidance documents

- Support the need for guidance documents
- Provide clarity to stakeholders on FDA's current thinking
- Both general and device specific guidance documents are essential
- Good Guidance Practices provide consistency in development, issuance and use of guidance documents

# Development of guidance documents

- Importance of seeking stakeholder input including experts during development
  - Public meetings, workshops, and small groups
- Consistency with international standards where appropriate
- When needed, FDA meeting with commenters to seek clarification before publication of final guidance



- Guidance documents involving stakeholder interactions during development
  - 1997 510(k) modifications
  - 2001 Least Burdensome
  - 1993 Heart Valve guidance document

- Identifying priority documents for development
- Identifying priority documents to finalize
- Documents implementing MDUFA/FDASIA should be top priority
- Priority List A should be a dynamic list based on stakeholder comments and need

# Updating current guidance documents

- Process for reviewing and updating documents needed
- Regular frequency should be established
- Obsolete or redundant documents should be removed after notification to stakeholders
- Guidance documents under revision should be flagged

- Adequate training of FDA staff needed on new guidance documents
- Draft guidance documents should be finalized in reasonable time frames
- Draft guidance documents should not be used as though final
- Deviations from existing guidance should have supervisory approval
- “Immediately in Effect” guidance when public health issues warrant the status



- GGPs were established to ensure consistency in the guidance process
- Stakeholder opportunities in the development of guidance documents yield quality guidance
- Training on use of guidance documents is essential
- AdvaMed supports the development of guidance documents