Medical Devices Regulatory Submissions - Best Practices

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Prior to the Submission

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Best Practice: Tools

- Areas of FDA-CDRH focus
- Q-Sub meetings
- FDA-sponsored training
- Guidance documents

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Best Practice: Tools

- Areas of FDA-CDRH focus
  - Metrics to inform regulatory decision-making
  - Clinical trial design for medical devices
  - Cybersecurity
  - Patient perspectives in regulatory decision-making

- Reference: http://www.fda.gov/downloads/MedicalDevices/ScienceandResearch/UCM521503.pdf

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Best Practice: Tools

- Q-Sub meetings
  - Pre-submission
  - Informational
  - Study Risk Determinations
  - Early Collaboration
  - Submission Issue

- Reference:
- http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf

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Best Practice: Tools

- FDA-sponsored training
  - FDA Regulatory Education for Industry (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm456382.htm)
  - Meetings, Conferences, Workshops , Webinars (http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/default.htm)
- Guidance documents
  - (http://www.fda.gov/RegulatoryInformation/Guidances/)

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Best Practice: Regulatory Strategy

- A documented plan of action
- A living document which is updated as a product development project evolves
- A communication tool
- In developing your strategy, take into consideration:
  - Emerging regulatory thought
  - Existing guidance
  - Literature
  - Information from the field

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Tools and Strategy Application: Delivery Devices

- Does our device need a clinical trial?
- Is our device a combination product with a drug or biologic?

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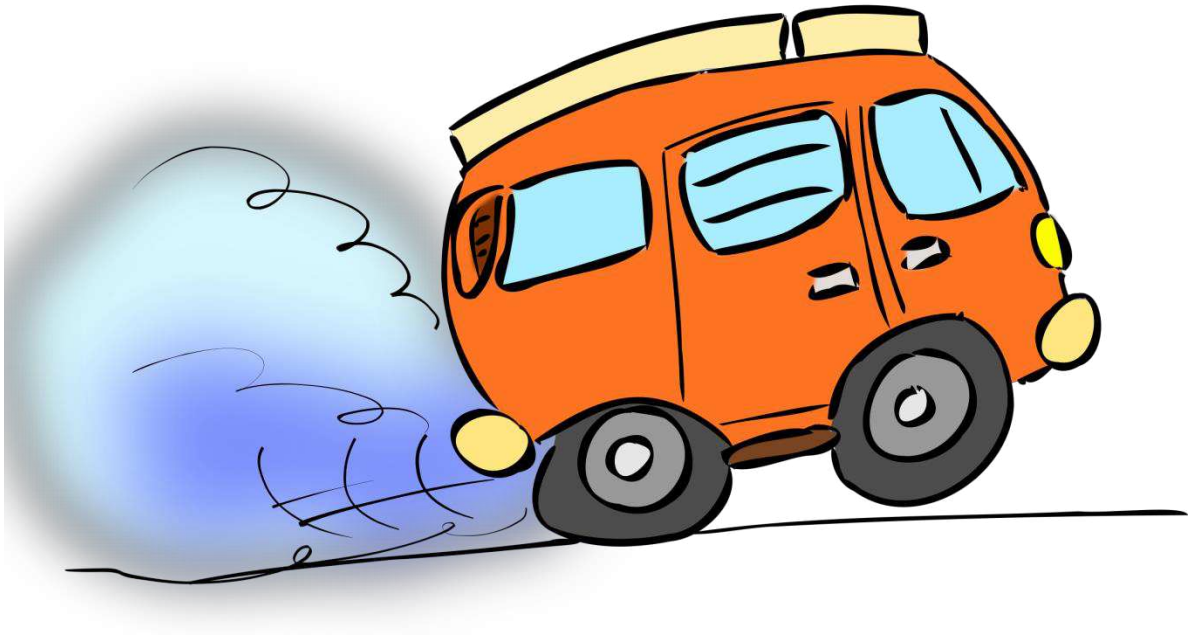
Developing the Submission



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Best Practices – Consistent and Thorough Submissions

- Develop an accurate and consistent message supported with data. Be consistent with this message throughout the submission.
- Anticipate reviewer questions and answer these as you write/ review submissions.
- Utilize checklists in guidance documents or on FDA's website.

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