The Role of Evidence in the Review of Infusion Pumps

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Infusion Pump Guidance

- **Infusion Pumps Total Product Life Cycle**
- **Guidance for Industry and FDA Staff**
- **Document issued on: December 2, 2014**

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- "The safety assurance case (or safety case) consists of a structured argument, supported by a body of valid scientific evidence that provides an organized case that the infusion pump adequately addresses hazards associated with its intended use within its environment of use. The argument should be commensurate with the potential risk posed by the infusion pump, the complexity of the infusion pump, and the familiarity with the identified risks and mitigation measures."

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- “Safety assurance cases are best developed in parallel with the development of the device. Constructing your safety case in concert with the device will not only allow for better safety controls, claims, arguments, and evidence, it may reduce the costs of retrospective mitigations if it is determined that a finished design is not adequately safe.”

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- "**Argument**: Links the evidence to the claim. Arguments can be deterministic, probabilistic, or qualitative. The argument describes what is being proved or established, identify the items of evidence you are appealing to, and the reasoning (inference, rationale) that the evidence is adequate to satisfy the claim. Arguments may also introduce sub-claims or assumptions which require further exposition. In addition to demonstrating that the evidence is adequate to satisfy the claim, the argument should also address the confidence in the sufficiency of the evidence."

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- **"Evidence**: Information that demonstrates the validity of the argument. This can include facts (e.g., based on observations or established scientific principles), analysis, research conclusions, test data, and expert opinions."

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- “Within a single safety case, there will be multiple layers of claims and arguments, with increasing levels of specificity as the safety case approaches the evidence level.”

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- “The safety case should then progress to establishing that causes of the device hazards are adequately addressed within its context of use and demonstrate through evidence the effective implementation of the hazard mitigations.”

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- "The amount and type of evidence required to support the indications for use and technology for a particular infusion pump varies. You should identify all of the evidence that you rely on to support your claims of safety and effectiveness and to provide confidence that the evidence selected is complete."

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- "In addition to evidence of conformity with one of these applicable standards, you should provide summary information in your premarket submission to FDA describing the following:…"

Miscellaneous

- Reliability Analysis -…" As part of the safety assurance case, the analyses and associated activities may take the form of claims, arguments, or evidence." pg. 20
- Electromagnetic Compatibility - …" In addition to evidence of conformity with one of these applicable standards…" pg. 21
- Software General Considerations - …"For example, if the problem was an off-by-one error in an array, provide evidence that all arrays were checked for off-by-one errors." pg. 23

Miscellaneous Cont.

- Software General Considerations - …" Provide evidence that a coupling analysis was performed to identify all parts of the software that accessed the anomalous code and that no problems would arise because of accessing this anomalous code." pg. 23
- Mechanical Safety General Considerations – "The evidence that you provide should demonstrate that the sources of the mechanical hazards are controlled and that the controls are effective. " pg 24

Miscellaneous Cont.

- **Clinical Investigation** – "The safety assurance case report should include evidence to demonstrate that the hazardous situation controls are effective….Appropriate evidence to validate the intended use of the device should be included in the safety case report." pg. 28