



Track D

Device Design Similarity and Testing Needed to Support Device Changes

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OINDP Device Change Management

1) Would a classification system for OINDP device changes help define the testing approach and regulatory pathway to support these changes?

If so, how could OINDP device changes be categorised? (e.g. air flow path and non-air flow path)

Who should decide when a scientific and technical justification for a change is adequate and acceptable?

2) Should industry be aiming to move towards increased self-regulation of activities, as in the case of Medical Devices? (based on Risk Management and Quality Management Systems)

If so, what are the blockers & enablers for this? What would the steps towards implementation look like?

Would improved industry performance standards and quality systems provide a mechanism for more transparent self-regulation?

Comments on Device Survey



- Lack of consistency in responses
 - More work required to investigate this
 - Did respondents answer based on what they would do or what they believed should be done
- Risk Management does not appear to be informing decision making
- Desire to see sub-analysis of responses e.g. by region, background, experience
- Interest in comparing survey responses to actual approaches that were taken by the scenario writers

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Communication



- Need for greater alignment of all stakeholders – Regulatory bodies, ISO, GHTF, ICH (e.g. uptake of ISO 20072)
- Encourage communications within regulatory agencies (e.g CDER, CDRH, OGD)
- Increased access to regulators – dialogue, information sharing and building trust
- Harmonised global approach – more convergence & consensus
- Engagement & management of supply chain (n-2, n-3 suppliers)

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OINDP Change Guidelines



Existing change guidelines and standards are insufficient

Desire for more specific OINDP change guidelines

- Flexible not prescriptive
- Based on Risk Management principles (ISO 14971 & ICH Q9)
- Approach to change based on assessment of impact on Critical Quality Attributes
- Appropriate technical input e.g. linking testing to clinically relevant parameters

Need to consider who should draft this guideline? How should it be co-ordinated?

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Risk & Quality Management Systems



- Consensus in the future relies on use of Risk Management & QMS
- How to earn trust and get regulatory buy in
- Are regulators prepared to allow manufacturers to oversee their own activities subject to a different type of regulatory control
- Who/How to create framework for increased self-regulation

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