MDSAP for the Medical Device Professional

Design and Development Module

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Agenda

- Intro to MDSAP Design & Development Module
- Review of Audit Tasks
- Internal Audit,
  Prep for AO

Intro to MDSAP Design and Development

- What comes first
- Objectives of the Module
- Purpose of Module Audit
- Outcomes of Module Audit
- Links to Other Processes

Design & Development: What Comes First

- Introduction to MDSAP
- Management Module
- Measurement, Analysis and Improvement

Objectives of Design & Development Module

- Understand purpose of the module
- Review expected outcomes from audit of the module
- Explain the 17 audit tasks
  - Including links to other modules
  - Including relevant country specific regulatory requirements
  - Including conformity assessment requirements

Design & Development Module - Purpose

- Verify the organization establishes, documents, implements, and maintains controls to ensure medical devices meet user needs, intended uses, and specified requirements

Design and Development Module - Outcome

Whether the organization has:

- Defined, documented and implemented procedures to ensure medical devices are designed according to specified requirements.
- Effectively planned design and development of a medical device
- Established mechanisms including systematic review, for addressing incomplete, ambiguous or conflicting requirements.
- Determined requirements for safety, function, and performance for intended use, incl regulatory, risk management, and human factors.
- Verified design outputs satisfy inputs

Design and Development Module - Outcome

Whether the organization has:

- Identified and mitigated, to extent practical, risks associated with device, including device software
- Ensure device design changes are controlled, risks associated identified and mitigated, to extent practical, and devices continue to perform as intended
- Performed design validation to ensure devices conform to user needs and intended use
- Confirmed designs correctly transferred into production via methods and procedures

Design and Development Module - Links

From Management

To Purchasing

To Production and Service Controls

From Measurement, Analysis and Improvement

To Device Marketing Authorisation and Facility Registration

Audit Tasks

- Task 1: Applying Regulatory Requirements
- Task 2: Select a Completed Project for Review
- Task 3: Design & Development Plan Review
- Task 4: Design & Development Procedure Conformance
- Task 5 & 6: Design & Development Inputs
- Task 7: Design & Development Outputs
- Task 8 & 9: Risk Management

Task 1: Applying D&D regulatory requirements

- Verifying devices with D&D requirements are identified
- Specific Country requirements:
  - Australia: devices not subject to D&D have technical documentation of meeting Essential Principles of Safety & Performance
  - Brazil: no design control exceptions…if design outsourced, complete DMR and records of design transfer to production
  - Canada: for devices exempt of D&D controls, evidence meeting 10-20 ER's

Task 1: Applying D&D regulatory requirements

- Assessing conformity:
  - Have devices, D&D requirements identified?
  - If devices/company exempt from D&D requirements, do records of this exist?
  - If absence of design activity, does organization have SOPs?

Task 1: Applying D&D regulatory requirements

- Link to Purchasing:
  - If design outsourced, is firm treated as supplier, qualified, controlled?
- Link to Management:
  - Evaluate top management's commitment to risk management activities. (e.g. implementation of new or more stringent controls, external controls (e.g. additional supplier-related controls), or design changes to maintain an acceptable level of product risk)
- Link to Device Market Authorisation & Facility Registration:
  - ensure that management is aware of requirements for device marketing authorization and facility registration, and that these are considered when designing the device. Confirm that management obtains marketing authorization in the appropriate jurisdictions prior to commercial distribution or design changes

Task 2: Review Completed Design Project

- Criteria for selection:
  - Complaints or known problems
  - Product risk
  - Recent design changes, changes to resolve quality problems
  - Age of design (in favour of more recent)
  - Design not recently audited

Task 2: Review Completed Design Project

- Link from Measurement, Analysis, Improvement:
  - If corrective actions resulted in design changes, or product nonconformities attributed to device design, consider selecting that design for review.
  - Be particularly mindful of how the identified quality problems from the Measurement, Analysis and Improvement process are related to specific aspects of the design and development of the device.
  - For example, if complaints related to a safety feature of the device that is not performing as intended, consider review the design verification of that safety feature and determine whether appropriate risk control methods were confirmed to be effective

Task 3: Design & Development Planned/Controlled

Include Country Specific Requirements:

- Australia: planning typically via a Quality Plan
- Canada: manufacturers of Class IV devices maintain a quality plan that sets out the specific quality practices, resources, and sequence of activities relevant to the device

Task 3: Design & Development Planned/Controlled

Assessing Conformity:

- Meeting country specific requirements as applicable
- Review design plan for selected project from task 2
- Does plan detail design and development activities, including assigned responsibilities and interfaces (especially if outsourcing)
- Did plan change as the design process evolved
- Were all plan changes documented and approved

Task 4: Design & Development SOPs Conformity

Include country specific requirements:

- USA: Design input procedures contain a mechanism for addressing incomplete, ambiguous, or conflicting requirements
- USA: requires independent design reviewer
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Task 4: Design & Development SOPs Conformity

Assess Conformity:

- Auditing country specific requirements as applicable
- Verify that the output procedure ensures that essential outputs are identified.
- Verify that the design review procedure ensures that each design review includes an individual who does not have responsibility for the design stage being reviewed.
- If no design project to review, has not made design changes, limited to review of SOP(s)

Task 5: Design & Development Inputs

Country Specific Requirements:

Australia: Verify that the manufacturer has identified the relevant Essential Principles that apply to the medical device

USA: For the selected device(s), verify that the organization has the appropriate marketing clearance [510(k)] or pre-market approval (PMA) if distributing the devices in the United States.

Task 5: Design & Development Inputs

Assess Conformity:

- Verify applicable country specific requirements
- For the design file selected:
  - Design inputs are established, reviewed and approved
  - Design inputs address customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements including those arising from human factors issues, essential for design and development.
  - Verify that any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process.

Task 5: Design & Development Inputs Address…

Links To Market Authorisation and Facility Registration:

- Regulatory requirements for registration, listing, notification and licensing are addressed, and manufacturer has complied with these requirements prior to marketing the device in the applicable regulatory jurisdictions

Task 6: Design & Development Inputs…

Assess Conformity:

- confirm the design inputs for selected project are complete, unambiguous, and not in conflict with each other
- Ensure these are inputs are covered:
- Intended use / user
- Performance Characteristics
- Risk mitigation
- Biocompatibility
- Compatibility of environment (EMC)
- Software
- Radiation protection
- Human Factors
- Sterility
- Post production/complaints

Task 7: Design & Development Outputs

Country Specific Requirements:

Australia: Confirm that documentation identifies whether relevant state of the art standards have been applied in full or in part. If standards have not been applied, ensure that the manufacturer has documented a rationale to explain why alternative methods have been applied to demonstrate compliance with the Essential Principles

Australia: For devices incorporating a medicinal substance, verify that documentation also identifies the data to be derived from tests conducted in relation to the substance, and its interaction with the device

Task 7: Design & Development Outputs

Assess Conformity:

- Verify applicable country specific requirements
- Outputs are traceable to and satisfy input requirements
- All outputs have been identified including:
  - Essential for device proper functioning
  - Device specifications
  - Manufacturing specifications
  - QA Testing specifications
  - Device labeling and packaging
  - Installation and servicing

Task 7: Design & Development Outputs

Assess Conformity:

- For medical devices that are intended to be sterile, design should ensure compatibility of the sterilization process with the device, compatibility of the device packaging and the sterilization process, ability of the device to be sterilized or re-sterilized, and (if applicable), rationale for adding the device to a product family covered by a validated sterilization process.

Task 7: Design & Development Outputs

Links to Purchasing and Production and Service Controls:

- For suppliers that provide products and services related to the essential design outputs, the degree of purchasing controls necessary is commensurate with the effect of the supplied product on the proper functioning of the finished device.
- consider reviewing production processes and supplied products that have the highest risk or greatest effect on the essential design outputs.

Task 8: Risk Management

Country Specific Requirements:

Brazil: Verify that the manufacturer has established and maintains a continuous process of risk management which covers the entire life cycle of the product. Possible hazards must be identified in both normal and fault conditions, including those arising from human factors issues. The risk associated with those hazards, shall be calculated. Risks must be analyzed, evaluated and controlled, as necessary. Effectiveness of risk controls implemented shall be evaluated.

USA: Confirm that the manufacturer has identified the possible hazards associated with the device in both normal and fault conditions. The risks associated with the hazards, including those resulting from user error, should be calculated in both normal and fault conditions. If any risk is judged to be unacceptable, it should be reduced to acceptable levels by the appropriate means. Ensure changes to the device to eliminate or minimize hazards do not introduce new hazards

Task 8: Risk Management

Assess Conformity:

- Verify country specific requirements
- Verify RM initiated early in design process
- Verify RM Process includes proactive evaluation, control, and monitoring of product risk, followed by the reactive response to quality data that indicates new or changing product risk.
- Verify records of risk management demonstrate that risks that have been identified as unacceptable have been mitigated to an acceptable level.

Task 9: Risk Management

Assess Conformity:

- Confirm that design verification and/or design validation includes assurances that risk control measures are effective in controlling or reducing risk.

Audit Tasks

- Task 10 : Design & Development Validation
- Task 11: Clinical Evaluation & Testing
- Task 12: Software Subject to Design & Development
- Task 13: Changes Controlled, Verified, Validated, Approved
- Task 14: Design Reviews
- Task 15: Changes Reviewed for Previous Products
- Task 16: Design Transfer to Production
- Task 17: Management Commitment to D&D

Task 10: Design Validation

Country Specific Requirements:

Brazil: Verify design validation performed under defined operating conditions on initial production units. Validation includes device testing under real or simulated use conditions. Validation includes software validation as necessary. Stability studies performed as necessary.

USA: Verify design validation performed on initial production units, lots or batches, or their equivalents. When equivalent devices used in final validation, document in detail how device was manufactured and how similar and different from initial production. Justify why validation results are valid. Verify validation under actual or simulated use.

Task 10: Design Validation

Assess Conformity:

- Verify country specific requirements
- Verify design specifications conform to user needs and intended uses
- Verify validation completed prior to commercial distribution
- Verify acceptance criteria in advance of validation activity
- Verify validation record includes result, identification of design, methods, date, individual performing test/validation.

Task 11: Clinical Evaluation

Country Specific Requirements:

Australia: Records of validation include clinical evidence as required by clinical evidence procedures

Task 11: Clinical Evaluation

Assess Conformity:

- Verify country specific requirements
- Review if design validation needs to include clinical evaluation, including testing under real/simulated use conditions
- Review if a clinical study was required, was performed, was successful
- Review if other evaluations (review of historical evidence) required
- If clinical evaluation required, it demonstrates user needs and intended uses, packaging and labeling met

Task 12: Software

Country Specific Requirements: None

Assess Conformity:

- Verify software development part of D&D plan or a separate plan
- Life cycle requirements for software must be defined
- Confirm software verification activities (unit, subsystem, integration, system functional testing) as applicable with acceptance criteria in advance and review test results
- Confirm software validation activities (either simulated or actual use) as applicable and review results

Task 13: Design Changes Controlled

Country Specific Requirements:

Australia: Verify that the manufacturer has a process or procedure for notifying the auditing organization of a substantial change to the design process or the range of products to be manufactured.

Australia: Verify that the manufacturer has a process or procedure for identifying a proposed substantial change to the design, or the intended performance, of a Class AIMD or Class III device, and to notify the assessment body prior to implementing the change

Task 13: Design Changes Controlled

Country Specific Requirements:

Brazil: If the medical device evaluated is already registered/notified with ANVISA, verify that the design change was correctly and promptly submitted to ANVISA for approval, when applicable.

Canada: Verify that the manufacturer has a process or procedure for identifying a “significant change” to a Class III or IV medical device. Verify that information about “significant changes” is submitted in a medical device license amendment application.

Task 13: Design Changes Controlled

Country Specific Requirements:

Japan: For the Marketing Authorization Holder, confirm if the Marketing Authorization Holder has submitted a new application, a change application, or a change notification to PMDA/ a Registered Certification Body, when applicable.

Japan: For the Registered Manufacturing Site, confirm if the site has a mechanism to communicate with the Marketing Authorization Holder about device modifications, so the Marketing Authorization Holder can take appropriate actions. If a critical medical device modification has happened in the Registered Manufacturing Site, confirm if the Registered Manufacturing Site has communicated with Marketing Authorization Holder about the change

USA: Verify that the organization obtained a new 510(k) or supplement to the pre-market approval if required.

Task 13: Design Changes Controlled

Assess Conformity:

- Verify country specific requirements
- Verify design changes applies to:
  - Inputs and outputs
  - Labeling and or packaging
  - To enhance product performance
  - Production Processes
  - From complaints/CAPA
- Verify change records include results of review of changes and updates to product specifications or changed processes are documented or amended.

Task 13: Design Changes Controlled

Links:

From/To Measurement, Analysis, Improvement (CAPA resulting in design changes, to correct quality problems, changes do not introduce new hazards)

To: Marketing Authorisation and Facility Registration: Changes impacting requirements for registration, listing, notification, licensing have been addressed prior to marketing the changed device in applicable jurisdictions

Task 14: Design Reviews

Country Specific Requirements:

USA:Verify that procedures ensure that participants include representatives of all functions concernedwith the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed.

Task 14: Design Reviews

Assess Conformity:

- Verify country specific requirements
- Verify design reviews:
  - At a minimum, at least one formal review
  - Typically at end of each design phase
  - Must have individual no direct responsibility for design stage reviewed

Task 15: Design Change on Previous Products

Country Specific Requirements: None

Assess Conformity:

When necessary, ensure the design change does not negatively impact products in distribution.

Task 16: Design Transfer

Country Specific Requirements:

Brazil:Confirm that the manufacture ensures that the design is not released for production until its approval by the persons assigned by the manufacturer and that the persons assigned review all records required to the design history file in order to ensure it is complete and the final design is compatible with the approved plans, prior to its release. Confirm that this release, including date and manual or electronic signature of the responsible is documented needed.

Brazil: Verify production specifications documented (in DMR) including device specifications, software source code, drawings, composition, BoM, production specifications, work instructions, environmental controls, measurement equipment, labeling and packaging, measurement and inspection tests with acceptance criteria, methods and procedures for installation and servicing (if applicable).

Task 16: Design Transfer

Assess Conformity:

- Verify country specific requirements
- Verify design transfer:
  - Design was transferred into production specifications
  - Review significant elements of the manufacturing processes, including products from suppliers and the established tolerances for processes, and compare them with the approved design outputs contained within the design records

Task 16: Design Transfer

Links:

To Production and Service Controls, Purchasing:

- ❑ Verify that production processes for the device, including process validation (if required) have been defined, documented, and implemented. Confirm that potential hazards that could be introduced or exacerbated by the production process have been identified, and production controls have been established. Production processes include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls.
- ❑ Confirm that the manufacturer has determined the type and extent of supplier controls based on the relationship between the supplied products and services and product risk

Task 17: Management Commitment to D&D

Country Specific Requirements: None

Assess Conformity:

Determine, based on the assessment of the design and development process overall, whether management provides the necessary commitment to the design and development process .

Internal Audit, Prep for AO

- Matrix of devices, countries with D&D specific requirements your company markets to
- Matrix of device designs, audit tasks, evidence
- Internal audit: Technically, IA to ‘MDSAP’ not required
- Internal (mock) audit: pick design that AO most likely to pick
- Internal (mock) audit: careful review of SOP(s) vs. requirements
- Prep for AO: if discrepancies in SOPs, records, revise, memos, etc.
- Prep for AO: Companion document good resource – also FDA Learn