PDP Services™
Medical Device Design Solutions

Whitney Moore, Director of Program Development
Aaron Lee, Manager of Quality and Regulatory
Ron Koronkowski, Director of Quality and Regulatory
# PDP Services™ - MEDICAL DEVICE DESIGN SOLUTIONS

1.0 Introduction .....................................................................................................................................................................3  
   1.1 Why PDP Services™? ................................................................................................................................................3  
   1.2 Quality System .........................................................................................................................................................4  

2.0 Design Control Regulation ...............................................................................................................................................4  
   2.1 FDA Guidance .........................................................................................................................................................4  
   2.2 Key Points of Design Controls ...............................................................................................................................5  
   2.3 Risk Management .....................................................................................................................................................5  
   2.4 Guidance on Timeline ..............................................................................................................................................5  

3.0 Nordson MEDICAL Product Development Process .........................................................................................................6  
   3.1 Alignment with FDA Waterfall .................................................................................................................................6  
   3.2 Best in Class Standardization ..................................................................................................................................6  
   3.3 Concurrent Engineering ............................................................................................................................................7  

4.0 Phases and Deliverables .....................................................................................................................................................8  
   4.1 Flow..........................................................................................................................................................................8  
   4.2 Phase 0: Concept and Feasibility ...............................................................................................................................9  
   4.3 Phase 1: Design Input ...............................................................................................................................................9  
   4.4 Phase 2: Design Process ..........................................................................................................................................10  
   4.5 Phase 3A: Design Outputs ......................................................................................................................................10  
   4.6 Phase 3B: Human Use ............................................................................................................................................11  
   4.7 Phase 4: Design Transfer .........................................................................................................................................11  

5.0 Benefits to Customer .......................................................................................................................................................12  

6.0 Conclusions ....................................................................................................................................................................12
1.0 INTRODUCTION

1.1 Why PDP Services™?

Nordson MEDICAL provides elegant and robust design and development solutions of finished devices. We recently established a new best-in-class Product Development Process, PDP Services™, that will help customers manage their business goals appropriately at the highest quality.

PDP Services™ forms the foundation of our expert Design and Development services. When combined with PDP Services™, regulatory compliance, high quality of output documentation, success through validation, and manufacturability and scalability, we consistently design medical devices that meet our customer’s expectations.
1.2 Quality System

We design and manufacture components and finished devices that have a direct and positive impact on the lives of countless patients around the world. From our line workers to our design engineers, we hold ourselves to the highest standards of quality.

Our quality mantra is Quality Works Here. This summarizes our commitment to world-class quality in everything we do:
- We take personal responsibility for quality
- We monitor and continually improve our Quality Management System
- We deliver customer-focused quality

There are four necessary parts of a quality system. These include:
1. Design Controls
2. Risk Management
3. Document Controls
4. Supplier Management

This white paper will go into detail on how the PDP Services™ incorporates design controls to ensure we deliver medical devices of the highest quality.

2.0 DESIGN CONTROL REGULATION

2.1 FDA Guidance

Guidance Document: 21 CFR 820.30 and sub-clause 4.4 of ISO 9001

The FDA's guidance document on Design Control for Medical Device Manufacturers has remained relevant and unchanged since its issuance on March 11, 1997.
2.2 Key Points of Design Controls

There are several key points of design controls, which serve as evidence that the product is safe, and meets user requirements. These include:

- Design and Development Planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Transfer
- Design Changes
- Design History File

It is important to show traceability between design controls, such as relating Design Outputs to Design Inputs.

2.3 Risk Management

Design Controls and Risk Management should be integrated during the design and development process. While Design Controls are intended to ensure a safe product, Risk Management identifies and mitigates potential issues. Both are necessary for design, development, and manufacture of medical devices.

2.4 Guidance on Timeline

When do Design Controls start? The FDA Guidance document says, "Design control begins with development and approval of design inputs, and includes the design of a device and the associated manufacturing processes." (21 CFR 820.30 p. 2)

When does Risk Management Start? The FDA Guidance document says, "Risk management begins with the development of the design input requirements." (21 CFR 820.30 p. 2)

When do Design Controls finish? According to the FDA Guidance document, "Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market.” (21 CFR 820.30 p. 2)
3.0 NORDSON MEDICAL PRODUCT DEVELOPMENT PROCESS

3.1 Alignment with FDA Waterfall

Because of the relevance of the FDA’s waterfall diagram Nordson MEDICAL has aligned the Product Development Process, practices and procedure requirements.

3.2 Best-in-Class Standardization

Nordson MEDICAL provides a vertically-integrated offering that includes design, development, and manufacturing of finished devices, from concept to launch. There are sites within Nordson MEDICAL that specialize in early concept development, so projects may begin in one site and then transfer to another when transitioning to manufacturing. PDP Services™ is also aligned on best practices to help our customers achieve their business goals. Aligning on phase structure and project chronology eases cross-site communication, project transitions, and project transfers between sites.
3.3 Concurrent Engineering

Concurrent engineering will allow customers to get to market faster and more efficiently.

The FDA Design Control Guidance for Medical Device Manufacturers explains the benefits of concurrent engineering, or ensuring the Medical Device design and PROCESS are developed in parallel.

"In a traditional waterfall development scenario, the engineering department completes the product design and formally transfers the design to production. Subsequently, other departments or organizations develop processes to manufacture and service the product. Historically, there has frequently been a divergence between the intent of the designer and the reality of the factory floor, resulting in such undesirable outcomes as low manufacturing yields, rework or redesign of the product, or unexpectedly high cost to service the product."

"One benefit of concurrent engineering is the involvement of production and service personnel throughout the design process, assuring the mutual optimization of the characteristics of a device and its related processes. While the primary motivations of concurrent engineering are shorter development time and reduced production cost, the practical result is often improved product quality." (21 CFR 820.30 p. 5)
4.0 PHASES AND DELIVERABLES

4.1 Flow

The purpose and requirements of each phase of PDP Services™ are detailed below. These are designed to ensure that your device will achieve your business goals and successfully get to market should Nordson MEDICAL continue to be involved or not.
4.2 Phase 0: Concept and Feasibility

**Purpose:**
- The purpose of this phase is to determine the feasibility of various concepts.

**Requirements:**
- Phase 0 does not require design controls and is not required to be part of formal development. The specific outputs for this phase are governed by the customer approved proposal.
- Document Revision = Concept

**General:**
- This phase is used to develop ideas and potential concepts that could be sculpted and formalized into a Medical Device. All aspects of this phase operate outside of design controls and are prior to understanding and having formally documented user needs and design inputs.
- The procedure establishes best practices for this phase to promote the appropriate documentation, however these deliverables are not required.

4.3 Phase 1: Design Input

**Purpose:**
- The purpose of this phase is to further develop and evaluate designs as well as establish project requirements information, project budget, and timeline. A plan will be created to outline the deliverables required to achieve the project goals and manage the associated risk.

**Requirements:**
- This phase initiates Design Control.
- Required deliverables:
  - DHF/Project File
  - Design & Development Plan
  - Design Inputs
  - Risk Management Plan
  - Phase 1 Design Review
  - Phase 1 Review
- Document Revision = Engineering (Numeric)

**General:**
- Phase 1 initiates the overall DHF or project file, any design related planning documents, as well as the FDA required Design Inputs document.
4.4 Phase 2: Design Process

Purpose:
- In this phase the product and the associated manufacturing processes are being designed and developed concurrently. Teams will establish target design requirements and select a design that can meet target specifications (Design Freeze) that includes an adequate manufacturing process.

Requirements:
- Initiates majority of the Documentation to control a design and its process.
- Required deliverables:
  - Risk Package (HA, UFMEA, DFMEA, PFMEA, etc.)
  - Manufacturing Documentation (MPI, Router, BOM, Flowchart, etc.)
  - Specifications (Component, Product, DMR, etc.)
  - Tolerance Analysis or confirmation of design intent
  - Phase 2 Design Review
  - Phase 2 Review
  - Document Revision = Engineering (Numeric)

General:
- Phase 2 establishes all documentation that is needed to move into verification/validation and ultimately commercial manufacturing.

4.5 Phase 3A: Design Outputs

Purpose:
- The purpose of this phase is to conduct design verification and validation testing to demonstrate that the design outputs meet the design input requirements.

Requirements:
- Phase 3A completes the V&V package to ensure a valid and verified design.
- Required deliverables:
  - Equipment IQ/OQ (Establishes Safety and Parameters)
  - Process Specification (Translates design intent into repeatable process requirements and parameters)
  - Design Verification plan and report
  - Shelf Life, Packaging, Transit, Biocompatibility plans reports
  - Sterilization plan
  - Design Validation (non-human use)
  - TMV Plan (DV tests)
  - Design Equivalency
  - Phase 3A Design Review
  - Phase 3A Review
  - Document Revision = Engineering (Numeric)

General:
- Phase 3A allows for the statement of, "The Medical Device (Design + Process) has been verified to effectively meet design intent and validated confirming the functionality required."
4.6 Phase 3B: Human Use

Purpose:
• The purpose of this phase is to manufacture human use (non-commercial) product that is production equivalent.

Requirements:
• Phase 3B finalizes any design documentation and confirms release criteria to allow for the manufacturing and shipment of Human Use product.
• Required deliverables:
  • Anything that was not completed in Phase 3A
  • Risk Management Report
  • Release or Acceptance Criteria (Certificate of Conformance, Sterile Batch Release, Lot Release, etc.)
  • Phase 3B Review
  • Document Revision = Engineering (Numeric)

General:
• This phase establishes controls to allow for non-commercial Human Use product shipment prior to the manufacturing process being fully validated.

4.7 Phase 4: Design Transfer

Purpose:
• The purpose of this phase is to demonstrate that the manufacturing processes used to produce the product are sufficiently developed, controlled, and qualified to transfer the product into commercial manufacturing.

Requirements:
• Phase 4 finalizes all process documentation and confirms validated state.
• Required deliverables:
  • Master Validation (Plan & Report)
  • Process and Test Validation (OQ, PQ, PPQ, PV, TMV, etc.)
  • Material Validation (Supplier, Component, etc.)
  • Manufacturing Agreements (Quality, Supply, Master Service, etc.)
  • Risk Management Report (if no phase 3B)
  • Design Transfer Review
  • Document Revision = Manufacturing (Alpha)

General:
• Phase 4 completes all requirements and documents readiness for full compliant commercial manufacturing.
5.0 BENEFITS TO CUSTOMER

PDP Services™ provides many benefits to customers. All customers benefit from:
• More efficient development process including collaborating with multiple sites, transitions/transfer between sites.
• Concurrent engineering will allow for shorter development time and reduced production cost, which often results in improved product quality.
• Better prepared for commercial manufacturing.

PDP Services™ can also adapt to different customer needs:
• Companies who are trying to get to market will also benefit from best-in-class PDP for regulatory submissions.
• Companies who are trying to get acquired will also benefit from best-in-class PDP for potential buyers.
• Companies who are still in Concept Development will see increased flexibility with Phase 0 outside of PDP, which allows Nordson MEDICAL to provide early concept deliverables more efficiently.

6.0 CONCLUSIONS

PDP Services™ is the new standard in medical device design and development. It balances efficiency, flexibility, and compliance at the highest quality. Whether in concept development or preparing to ramp to production, PDP Services™ will ensure that the medical device will meet all requirements, be safe for use, and achieve short-term and long-term business success.
About Nordson MEDICAL

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market. Visit Nordson MEDICAL at nordsonmedical.com.