Introduction

NILE is a contract manufacturer of tailored printed, converted and assembled products used within different business areas.

The tailored product(s) are often a based upon several complex manufacturing processes.

In general NILE develop tailored products together with the client, often with specific individual client needs and under a Confidential Partner Collaboration.
The product(s) are developed with the aim of commercialization and volume production.
Note that NILE do not develop product(s) together with the client intended to be manufactured by someone else. The client owns the right of the product specification, whereas NILE owns the IP recipe needed to manufacture the product. The client also owns the full responsibility of the product's use and performance, including assessing fitness for use in the medical device or application. The client obtains the appropriate regulatory approvals.

NILE owns the responsibility to manufacturing the product(s) with the controls and routines that are needed for the product, including client requirements.

NILE understands that the client might not have all requirements and specifications ready when initially starting up the cooperation with NILE. This as some requirements and knowledge input for the specification is taught and understood during the development Phase.

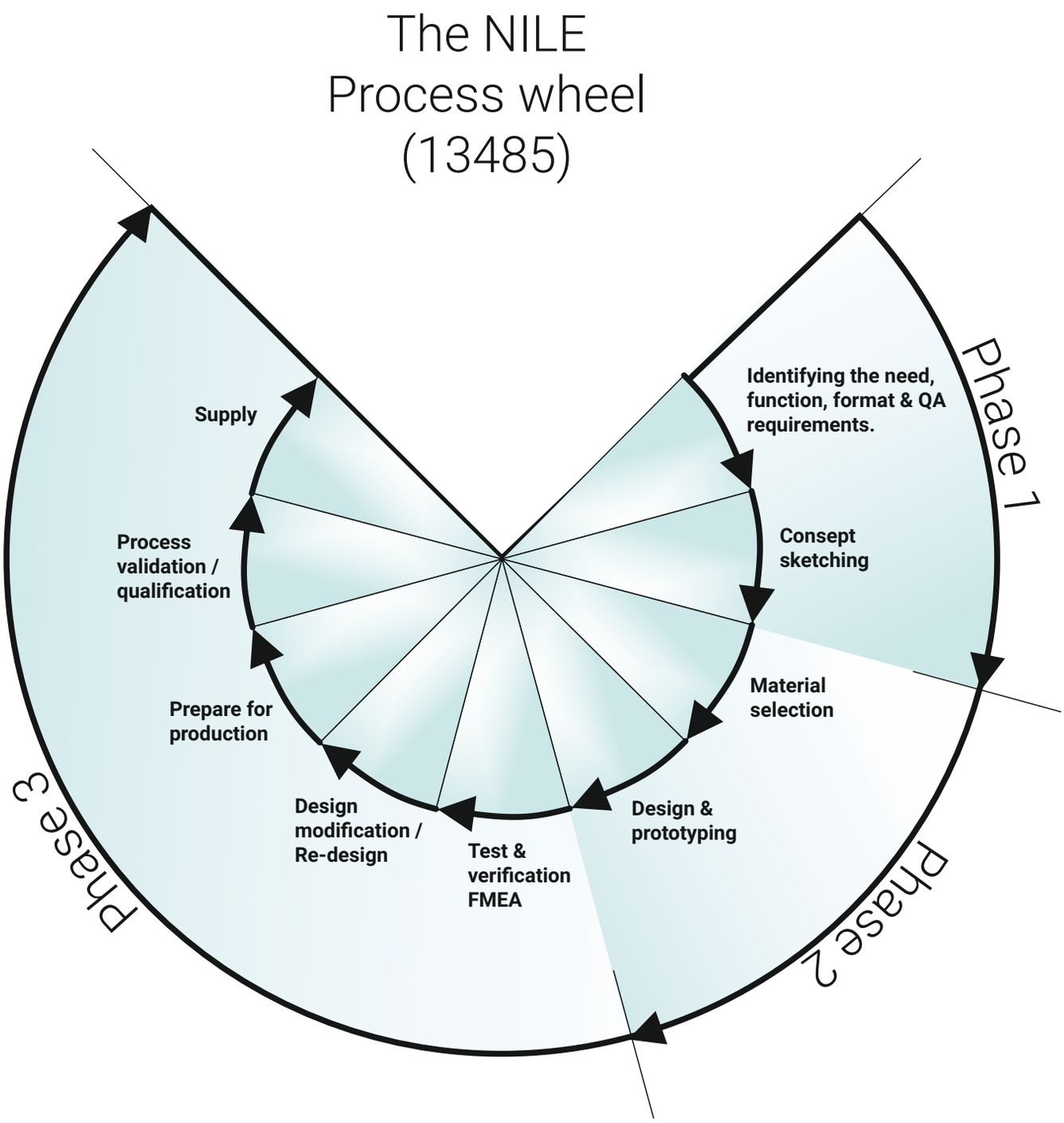
However, it is important that the product specification and specific manufacturing requirements are set before the product is approved and released for supply.

During the development process, several phases will be affected, all with different needs of requirements. After each phase NILE and client will make a joint Go/NoGo decision.

On the next two pages we will try to visualize our product development process, clarifying the responsibility for the different actions needed in each phase.

Ownership	NILE	CLIENT
-Product Specification		✓
-Manufacturing Specification	✓	
Area of Responsibility		
-Manufacturing process	✓	
-Product Design		✓
-Product Functionality		✓
-End user interface		✓
-Regulatory approvals		✓

The process visualized



Phases explained

Phase 1.
Creating and agreeing on a scope and project plan

Area of Responsibility	NILE	CLIENT
-Brainstorming activities		
-Concept ideas	✓	✓
-Material functionality requirements	✓	✓
-Material environmental requirements (REACH/RoHS)		✓
-Proposing materials		✓
-Proposing design	✓	
-Specific QA/RA requirements	✓	✓
-Time frame		✓
-Volume and price estimations		✓
	✓	

At this stage the client is often charged for running costs based upon hourly charge.
Monthly time reports are provided with the Invoice.
Fix price can be quoted prior to starting up this Phase.

Phase 2.
Engineering and prototyping

Area of Responsibility	NILE	CLIENT
-Creating engineering drawings in 2D (3D if needed).	✓	
-Creating and sending proof to client	✓	
-Approving and signing proof		✓
-Defining materials and provide client with material specifications.	✓	
-Defining environmental and/or product specific requirements.		✓

Nile will only materials that are biocompatible for layers that will be in contact (or near contact) with skin.

The product(s) delivered in this phase are not fully representing the roll to rollmanufactured later manufactured products, as the samples will be produced in our R&D laboratory, delivered on sheets. No material and production traceability are used in this phase.

At this stage the client is often charged for running costs based upon hourly charge.
Monthly time reports are provided with the Invoice.
Fix price can be quoted prior to starting up this Phase.

Phases explained

Phase 3.
Preparing product for supply

Area of Responsibility	NILE	CLIENT
-Creating Production Process Specifications (Work Instructions).	✓	
-Finalizing first revision of Risk assessment - (P)FMEA	✓	
-Defining control plan	✓	
-Finalizing BOOM	✓	
-Finalizing Labeling specification	✓	
-Finalizing Packaging specification	✓	
-Tool Validation	✓	
-Process Qualification PQ1-PQ3	✓	

Phase 4.
Preparing medical product for commercialization

Area of Responsibility	NILE	CLIENT
-DMR (Device Master Record)		✓
-DHF (Design History File)		✓
-List of Harmonized standards		✓
-Design Risk Assesment		✓
-Risk Assesment in accordance with ISO14791		✓
-Declaration of Conformity		✓
-Biocompatibility test report		✓
-Ageing test report (if applicable)		✓
-Clinical testing from a safety prespective		✓
-User Instructions		✓
-FDA-registration & approval		✓
-CE-registration & approval		✓

Phase 4 belongs to the client, but in some cases, Nile supports the client in several of these areas. Let us know if you lack experience and/or resources for any of those tasks and we'll investigate to see if and how we can help out.