**Quality Plan**

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# Purpose

This document outlines the quality plan for the Respira Works ventilator system. It covers the development quality plan of the device which will be followed from concept phase, through design development, it does not cover the design transfer phase or manufacturing quality.

# Definitions

1. Design Input – Safety, physical, and performance requirements of a device that are used as a basis for device design.
2. Design Review – evaluation of outputs to review completeness and accuracy of design.
3. Design Verification – Confirmation that design output specifications conform to design input requirements.
4. Design Validation – Confirmation that the device conforms with defined user needs and intended uses
5. Design History File (DHF) – compilation of records related to the design of a device.
6. Device Master Records (DMR) – records and specifications that define the procedure for production of a device.
7. Specification – Any requirement with which a product, process, service, or other activity must conform.
8. User Needs – Qualitative inputs that consider the needs of the user including usability, capability which inform indications for use of the device as well as inputs for design.

# Project Phases

The ventilator development effort will be broken into several phases to ensure that inputs and development outputs are clearly defined at each phase and will be included in the design history file (DHF). These phases will be closed with a phase review prior to the conclusion of the proceeding phase. The deliverables in the previous phase can be revisited after the phase has been closed provided a proper regression analysis analyzing the impact of modifications is performed. These phases consist of:

* Design Planning and Definition Phase
* Design Development Phase
* Verification / Validation Phase
* Design Transfer

## Design Planning and Definition Phase

This phase consists of developing a plan for the design of the device and defining the device inputs. The outputs of this phase is a development plan, user needs analysis, user risk analysis, and design inputs.

## Design Development Phase

This phase consists of producing engineering outputs including subsystem requirements, engineering specifications (CAD drawings, circuit schematics, source code, etc..), and a design risk assessment.

## Verification/Validation Phase

This phase includes defining verification / validation test methods and the performance of these test plans. The output of this phase is a verification and validation test report.

## Deliverable Overview

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| **Deliverable** | **Design Planning Phase** | **Design Development Phase** | **Design Verification/Validation Phase** |
| Development/Quality Plan | Creation/Review |  |  |
| User Needs | Creation/Review |  |  |
| Design Inputs | Creation /Review | Update |  |
| System Risk Analysis | Hazard / Source Identification | Mitigation Development | Risk Control Analysis / Report |
| Design Specifications |  | Creation/Review |  |
| Design Risk Assessment |  | Creation/Review |  |
| Design Verification Plan / Report |  |  | Creation / Review |
| Design Validation Plan / Report |  |  | Creation / Review |

# Design History File (DHF)

The Design History File (DHF) shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the quality plan. All phase deliverables, design reviews and other applicable design information shall be kept in the DHF. The quality lead is responsible for keeping accurate record of the DHF