open.PAPR

Execution & Quality Plan

01 Authorization

Role	Name	Date	Version	Signature
Author	Ralph Lawrence Wunderlin	20200415	01	
Reviewer	Paul Kindt	20200415	01	

02 Change Log

Version	Author	Date	Reason
01	Ralph Lawrence Wunderlin	20200415	First Revision 🐻❤️🌟

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03 Scope of this document

This document contains the procedures that are to be followed to execute the open.PAPR project in a transparent and traceable manner.

It also is the milestone for the start of the design and execution phases. The project will be closed out with a Execution & Quality Report. The report will state what has been achieved, and any changes and deviations that may have occurred.

04 Roadmap

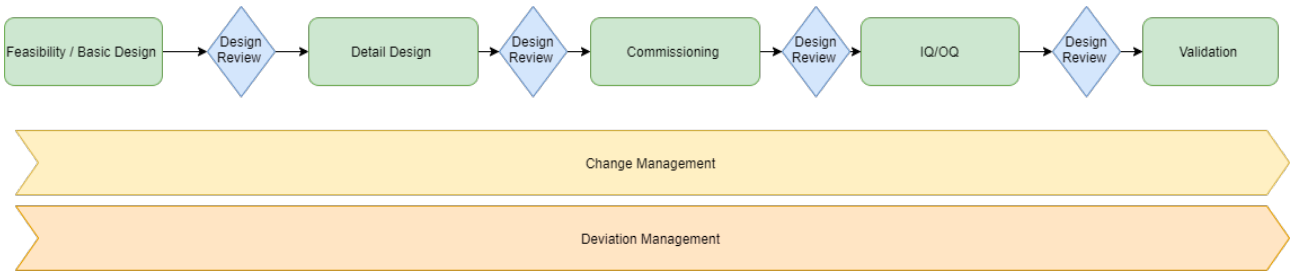

Diagram 01: Project Roadmap with milestones and CM/DM

04.1 Initiation and Closure

The project is initiated with the approval of this document and closed with a Project Execution & Quality Report.

04.2 Design Review

Design review is a must between every project phase.

This step ensures that the approved requirements have been checked against specifications. To speed this up, one shall reference approved requirements in it:

open.PAPR Requirements-V01		
No	**Category**	**Requirement**
R-example1	Business	The Filter and Fan Unit must contain at least one fan or blower
open.PAPR Instrument list		
Position	**Name**	**Description / Note**
M01	Main Blower	This blower transports air through the unit (R-V01-example1)

Table-01: Design Review Example

This step may generate Change Requests or Deviation Reports.

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There should be no Deviation Reports unresolved before releasing to the next phase.

Release to the next phase is done with the open.PAPR-Traceability Matrix.

This document is updated and its version incremented at every design review step.

All documents and their versions must be listed in the document list, only the final version of a specification, drawing, etc. is used to check against the requirements and listed in the traceability matrix.

Checking the requirements must be done in .pdf format with annotations, these are to be attached to the signed traceability matrix.

04.3 Feasibility / Basic Design

Feasibility is given as there are commercial products available.

Minimum deliverables for closure of BD:

Document	Status	Comment
open.PAPR-Execution & Quality Plan	Reviewed & Approved	
open.PAPR-Requirements	Reviewed **&** Approved	
open.PAPR-Document List	Reviewed & Approved	All BD documents listed
open.PAPR-Org Chart	Updated	Including responsibility
open.PAPR-Media Flow Diagram	Draft	
open.PAPR-Risk Analysis	Reviewed & Approved	Status BD
open.PAPR-Traceability Matrix	Reviewed & Approved	All listed requirements checked: open.PAPR-Execution & Quality Plan; open.PAPR-Requirements Any CR's/DR's and their status

04.4 Detail Design

Document	Status	Comment
open.PAPR-Media Flow Diagram	Reviewed & Approved	
open.PAPR-P&ID	Reviewed **&** Approved	
open.PAPR-Instrument List	Reviewed & Approved	
open.PAPR-Bill of Materials	Finalized	

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Document	Status	Comment
open.PAPR-Functional Specification	Reviewed & Approved	Maybe SDS/SMDS spawn from this
open.PAPR-Source Code	Finalized	
open.PAPR-Wiring Diagram	Reviewed & Approved	
open.PAPR-CAD Hood	Reviewed **&** Approved & 3D-Printed	
open.PAPR-CAD Filter Fan Unit	Reviewed **&** Approved & 3D-Printed	May include battery compartment. If not: Separate CAD for battery compartment(s), same status
open.PAPR-Risk Analysis	Reviewed & Approved	Status DD To b executed as soon as the P&ID and CAD/3D-Prints are ready
open.PAPR-Document List	Reviewed & Approved	All DD documents listed
open.PAPR-Org Chart	Checked	
open.PAPR-Operating Manual	Reviewed & Approved	All relevant information contained, aim for CE
open.PAPR-Factory Acceptance Test Protocol	Reviewed & Approved	
open.PAPR-Traceability Matrix	Reviewed & Approved	Updated with DD-Information

05 Review and Approval

All documents must be signed and approved by the author and at least one reviewer. From an approved version of a document to a new revision there must be a reason given. Valid reasons: Termination, a change or a deviation.

06 Change Management

Changes to the project scope must be initiated with an approved Change Request. The feature used in this project will be the Github incident reporting system with a custom template.

07 Deviation Management

Deviations must be avoided, but if there is a deviation it always must have a reason, a proposed solution and approval. The feature used in this project will be the Github incident reporting system with a custom template.

During testing a seperate deviation management form will be provided. The feature used in this project will be the Github incident reporting system with a custom template.

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08 CSV (Computer System Validation)

Any part of the system that has a parameter set or a uniquie software must be validated. The classification of each device with such functionality must be defined in the functional specification and judged under GAMP 4 or 5. Established languages (C, C++, µP, etc.) must be source-code reviewed, standard libraries are exempted.

09 Project Closeout

10 Code of Conduct

10.1 Our Pledge

In the interest of fostering an open and welcoming environment, we as contributors and maintainers pledge to making participation in our project and our community a harassment-free experience for everyone, regardless of age, body size, disability, ethnicity, sex characteristics, gender identity and expression, level of experience, education, socio-economic status, nationality, personal appearance, race, religion, or sexual identity and orientation.

We shall all work in a concentrated, transparent and honest way to ensure a quick and successful delivery.

10.2 Our Standards

Examples of behavior that contributes to creating a positive environment include:

- Following the principles „What does good look like?
- Using welcoming and inclusive language
- Being respectful of differing viewpoints and experiences
- Gracefully accepting constructive criticism
- Focusing on what is best for the community
- Showing empathy towards other community members
- Following the guideline defined in the project plan
- Democratic decisions on details, if tied the lead decides - or flips a coin

Examples of unacceptable behavior by participants include:

- The use of sexualized language or imagery and unwelcome sexual attention or advances
- Trolling, insulting/derogatory comments, and personal or political attacks
- Public or private harassment
- Publishing others' private information, such as a physical or electronic address, without explicit permission
- Other conduct which could reasonably be considered inappropriate in a professional setting
- Not following the guidelines laid out in the project execution and quality plan, especially those concerning good documentation practice and deviation management

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10.3 Scope

This Code of Conduct applies both within project spaces and in public spaces when an individual is representing the project or its community. Examples of representing a project or community include using an official project e-mail address, posting via an official social media account, or acting as an appointed representative at an online or offline event. Representation of a project may be further defined and clarified by project maintainers.

10.4 Enforcement

Instances of abusive, harassing, or otherwise unacceptable behavior may be reported by contacting the project team at mondkind@mondkind.ch.
All complaints will be reviewed and investigated and will result in a response that is deemed necessary and appropriate to the circumstances.

The project team is obligated to maintain confidentiality with regard to the reporter of an incident. Further details of specific enforcement policies may be posted separately.

Project maintainers who do not follow or enforce the Code of Conduct in good faith may face temporary or permanent repercussions as determined by other members of the project's leadership.

10.5 Attribution

This Code of Conduct is adapted from the Contributor Covenant, version 1.4, available at https://www.contributor-covenant.org/version/1/4/code-of-conduct.html

For answers to common questions about this code of conduct, see https://www.contributor-covenant.org/faq

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11 Conventions

11.1 File management

11.1-1 GENERAL GOOD DOCUMENTATION PRACTICE RULES

All documents must have a reference to the source requirement.

All documents must be listed in the overall document list.

All documents have a defined integer version.

All documents must be numbered in the format Page x of n

All tables, figures and pictures in documents must have a footnote.

Abbreviations can be listed in documents, but this is not a must if the abbreviation is common knowledge (i.e. ISO).

Duplicate information must be avoided with great care.

11.1-2 LOCATION

The primary location of finalized documents is the GitHub repository.

Drafts *should* be saved daily in the repository as well (use the folder drafts in the active project phase).

Documents are separated according to the phase the project is in. Further description of the phases will be provided as a separate chapter in this document.

11.1-3 TEMPLATE

For text documents and coversheets for other files (drawings, etc.) the current pages template shall be used. It shall reside on in repository in the folder „_template“.

Coversheets must contain a reference to the document that is attached to them. A template for this shall be available in the drafts folder of the repository.

11.1-4 FILE NAMES

Final version:	open.PAPR-*Document*-*Revision*
Draft version:	JJJJMMDD_open.PAPR-*Document*-*Future revision*

11.1-5 TIME AND DATES (ISO-8601)

Dates are to be noted in the format	JJJJMMDD.	Example:	20200413
Alternative: DD, MMM JJJJ.		Example:	13. APR. 2020

11.1-6 TIME (ISO-8601)

UTC format shall be used. An exception can be made if there is a reference to UTC for every field, where one must a point in time.

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The project must be finalised with a report that refereces the chapters defined in this plan and declares all actions taken to reach the state, where the project can be closed.
The project can be closed due to: Completion of the objectives (all deviations must be resolved) or a project change to terminate the project. Closure is possible at any milestone.

12 Copyright

Solely CERN-OHL-P is the license used for this project.

12.1 Copyright notice applicable to this document

See front page and CERN-OHL-P Documents supplied with this package.

The file „CHANGES.TXT“ mentioned in the CERN-OHL-P how-to is replaced by the Change Log as defined in Chapter 5.