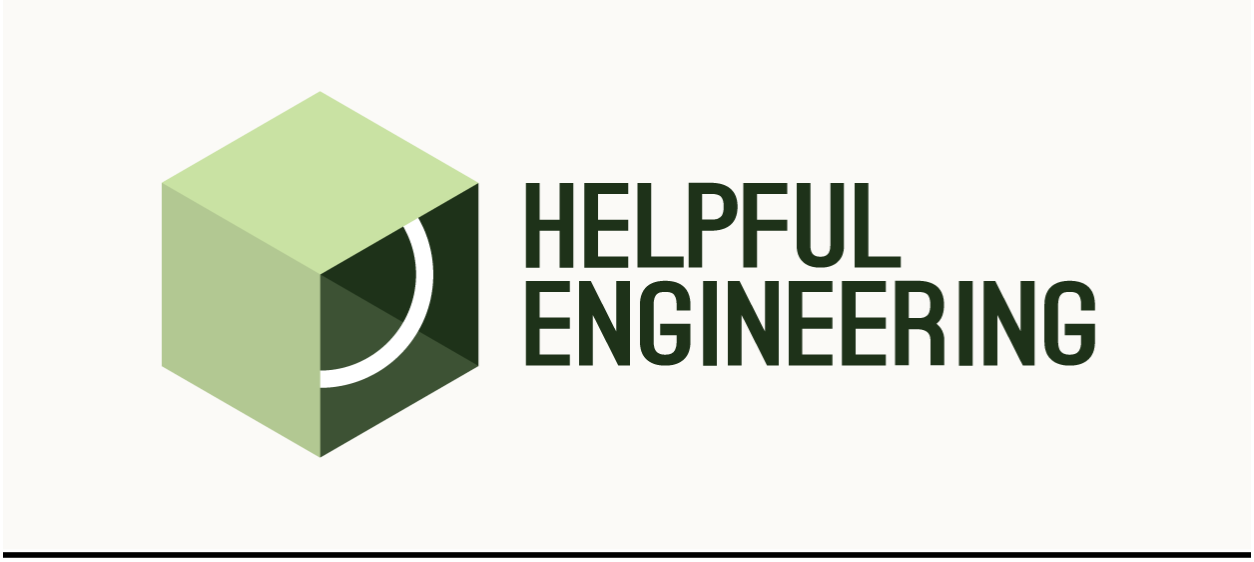

Helpful Engineering Proposal Submission template

Please note: This proposal will be made publically available after submission to HE, as part of an open-source repository.

Project Name	**open.PAPR**
Date	20200413
Owner(s)	Ralph Lawrence Wunderlin
Project Slack Channel	#project-open-papr (existing)

COVID Alignment

Mission Alignment

How is your project aligned with Helpful Engineering's mission to combat COVID-19? Please make a brief introduction to your proposed solution and argue how it is highly aligned with Helpful's mission. Assume the reader is familiar with COVID, but not familiar with your particular project.

- **Greatly reduces risk of contamination for the medical staff**

- **Personal protection equipment is insufficient and in short supply**

- **Provide medical staff with the protection they need**
  not just *whatever is on hand*

- **Decontamination after leaving the red-zone can be implemented**

The US CDC and the German Robert Koch Institut have designated PAPR's as an alternative to N94 masks:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Ressourcen_schonen_Masken.pdf

Impact

Overall Impact

Helpful's members are here to make a difference! Help the reviewers understand what your project's impact -- when successful -- will be on the pandemic. Cite evidence to support your claim if you can. Attempt to quantify the amount of people you help, using rough estimates if evidence is not available.

Loose doctors and nurses, even the janitor and the cleaning lady?
You've lost your hospital.

In Germany at least three hospitals had to be closed due to infected staff.

In Italy, 20% of the healthcare workforce have become patients - confirmed cases (https://www.medscape.com/viewarticle/927811#vp_2)

First responders are often unwillingly exposed to SARS-COV-2 to asymptomatic carriers and patients with unclear symptoms.

PAPR's can be specified, designed and built in a way that makes them re-useable.
Even in-line sterilization with EtO or vaporized H2O2 is a possibility.

Initial costs are high for commercial devices and spares like filters, etc.

The project shall deliver a working, validated design that comes at lower cost, can be manufactured in great numbers and is not tied to one vendor for filters,

Also - the requirements I have compiled state, that the device must be partially water tight, so that wet decontamination / decontamination shower is possible.

This is a massive difference to N95 or FFPx masks.

The masks are used against their standards currently - due to short supplies.

Doctors and nurses get one mask a day, not one mask/positive patient. Not one mask/n hours.

Masks also leave the face unprotected, hence the faceshields (some with questionable regulatory compliance) are being printed worldwide.
But: The risk when putting on a mask, using it (don't touch it, no beard, ensure close fit, etc) and taking it off pose a risk.

Every time a mask is used, doffing poses a risk: https://reference.medscape.com/medline/abstract/30029796

They do not impact sterility during operations: https://reference.medscape.com/medline/abstract/31519477 *(are you sure that motorcycle accident-patient is negative?)*

Pregnant and infected with SARS-COV-2? Emergency cesarian section. Done **safely** with a PAPR: https://www.ncbi.nlm.nih.gov/research/coronavirus/publication/32229802

Who knows if SARS will reappear like it disappeared? PAPR's where used then too: https://reference.medscape.com/medline/abstract/15560695

Furter reading:
https://www.ncbi.nlm.nih.gov/books/NBK294215/pdf/Bookshelf_NBK294215.pdf

Helpful's Role

Why are you proposing this to Helpful's community? We want to engage in projects where the skills and talent of Helpful's members can make a profound difference in the success or failure of your ability to execute.

> Applicable standard in Europe is EN 12941; in the US 42 CFR 84
>
> PAPR's are complex devices, not quite as complex as a ventilator, but there are constraints and requirements to be met. The community of HE is large, and there are experienced and committed engineers on board.
>
> It is impossible to execute this project without the right people in the right place. Alone? No way.
>
> This project is aiming for an open design that complies with both US and EU regulations, is low cost, near-failsafe and readily available, certified filters can be used from at least three different manufacturers.
>
> **What does good look like is the ethos, next to full transparency and regulatory approval with the medical staff in mind.**

Technical Viability

Scientific Feasibility

Is the science behind the solution sound? Convince readers who don't have deep expertise in your field that your innovation is built atop sound scientific and engineering principles. Point to the foundational and proven technologies that you rely on to deliver your solution.

> I kindly forward you to US 42 CFR 84, goal is a device compliant with the requirements to PAPR100-N.
>
> We are not reinventing the wheel, but making it readily available.

Speed

Time to Impact

The pandemic is moving fast and has a head start. How quickly can your solution begin to impact the problem it solves? Try to provide best case, worse case and average case estimates.

Best case:
- Design complete in 4 weeks, first prototypes up and running
- Design review done one week later
- Either be the manufacturer and/or find manufacturer(s) by mid-project
- Regulatory approval within 1 month from ramp-up by the manufacturer(s)
- Regulator supports the project as stake-holder/design reviewer, etc.

Worst case:
- Never get our of storming phase
- Project dead

Average case:
- Two months until regulatory approval

Scaling to High Volumes

How quickly can your solution be scaled to high volumes? This second aspect of speed is of crucial importance to Helpful and for pandemic responses in general.Try to provide best case, worse case and average case estimates.

Best case:
Very fast as soon as the case(s) and the hood can be injection molded. This takes about 1-2 weeks for tooling, then first tests and regulatory approval in parallel with final trial-batch.

Worst case:
See Boeing, SC

Average case:
Best case plus two weeks

Team

Team Membership

Do you have the key people and core capabilities you need to get to the next few milestones? If not, convince judges you have a credible recruiting plan and can fill personnel gaps.

I thought I had the support I needed, until my pal dropped out today.

Next milestone is finalizing BD - getting the requirements aligned and finalizing the Execution and Quality Plan. The E&Q Plan is essential, as this is a project that shall deliver a product that meets regulatory standards. So some kind of Q-process must be defined to ensure complete, full traceability.

Why HE should look for available, committed resources for this project? See Impact, see Feasibility.

Execution to Date on this Project

How has your team executed as a group on this project? What milestones have you accomplished as a group so far?

> This form, a near-final draft of requirements and a 90% ready Quality and Execution Plan.
>
> Attached to this PDF

Project Needs vs. Helpful Talent

For all of the below, if you have needs in this area, please pitch for Helful's assistance. Explain what you need and why it will allow your project to progress.

QA/RA Needs

> I am an experienced Instrumentation and Controls Engineer with about 20 years of Pharma behind me, about 2 years as lead automation engineer on about a dozen projects. HAZOP/ ZHA and GMP RA's are nothing new to me, we self-certified new and critical synthesis steps in the company I worked for.
>
> It definitely needs QA support, as it is a complex PPE. Having regulatory approval as a goal is tough.
>
> RA's - I yet need to find one that really applies to this PPE, otherwise classic ZHA would be my proposal - this requires at least the leads of the different work streams as a team (QA-Regulatory, Instrumentation & Controls, Process, etc)

Financial Needs

First: Quite some hours to get the design done and first prototypes printed.
If we go for EN 12941, the standard itself costs about 400 USD.

I personally would print prototypes for free, blower and the other parts required I would self-finance too for a prototype.

The regulatory cost is tbd, it will be far greater than the prototypes - but required. If we are lucky, a regulator or a designated lab could support the effort.

I will try to get the prototype tested (not validated) here in Switzerland by a large Pharma company I used to work for.

Recruiting Needs

- Second PM
- 2 QA-USA (and QA-EU if we can source the EN12941)
- 2 Mechanical designers (Solidworks, including simulation)
- Electronics: Two engineers
- Legal: At least one US representative (and two in the EU)
- Prototype printers: Three would be ideal
- One compliance engineer

Technical Expertise Needs

Air system design
System design
Device regulations (CE, etc)
Electronics
QA, Legal
Support (compliance)

Medical Expertise Needs

See Recruiting

Connection/Media Needs

- USA: Governors of hardest-hit states and lower ranking officials -> get them on board/keep updated
- EU: RKI/Baua Germany

- Media coverage as required.