IRON ROOSTER

Quality and Regulatory Affairs

The IronRooster Way

WHITEPAPER

INTRODUCTION

IronRooster has been in the SAMD world for almost 2 decades now, during which time hundreds of projects have seen the day of light with a wide variety of complexity as well as attention from various regulatory bodies. Earlier collaborations were limited to being outsourcing partners of the actual IP owners and our involvement with those projects only slowly stepped beyond software development and testing activities. As our clients' confidence grew in our teams and their dedication to provide quality work, more and more indirectly associated responsibilities started shifting to our side. This was not only a great way to be granularly introduced to the big picture, but it also allowed gathering experience that could be a welcome benefit to our other projects or other clients as well.

The department of Quality Affairs may be a relative newcomer within the company structure, but the knowledge accumulated there has been gathered and nurtured, utilized and tested for a long time.

This white paper is meant to present what we do and how we master being the best partner we can be.

HISTORY

Quality, as the famous saying goes, is “doing it right when no one is watching”. It is not surprising that it was Henry Ford, one of the most significant people in modern standardization history, who coined that phrase. Today there is no way getting around standards that can be used to define and describe all aspects of production and servicing activities in any industry.

Their practicality is undeniable for multiple reasons. They not only help entrepreneurs building companies and teams that work without the risky and tedious effort of learning efficiency and traceability from first-hand experience, but they are also the hallmark of quality through the periodic inspections of external evaluators, whose only job is to provide unbiased confirmation that your processes and output will not harm or deceive your customers.

IronRooster’s field of expertise is in healthcare, one of the most, if not the most regulated industries. When you are developing software that assists medical practitioners, software that stores and processes data, completes calculations, proposes decisions that are affecting the very life of patients or even healthcare providers themselves, there is no such thing as too cautious. The primary goal of standards and regulations is to minimalize risk to the wellbeing of those relying on the correct functionality of the medical device.

STANDARDS

There is no shortage of international or localized guidance documents and regulations to comply with in order to produce a safe product. The majority of our clients are located in the U.S. bringing us into FDA regulated territories as well as in Europe, where the recently revised MDR set the requirements for certified companies or their production activities. Whereas the Food and Drug Administration is an agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices, the EU Medical Device Regulation is a legislation that incorporates its predecessor, the Medical Device Directive with the EU harmonized standards and the ISO 13485 (Medical devices – Quality Management Systems – Requirements for Regulatory Purposes) standard in the European Union.

Besides the aforementioned example, the most commonly followed standards in this segment of the industry are:

• ISO 9000, Quality Managements Systems – Fundamentals and Vocabulary;

• ISO 14971, Medical devices – Application of risk management to medical devices;

• IEC 62304, Medical device software – Software life cycle processes;

• IEC 62366-1, Medical devices – Application of usability engineering to medical devices;

STANDARDS

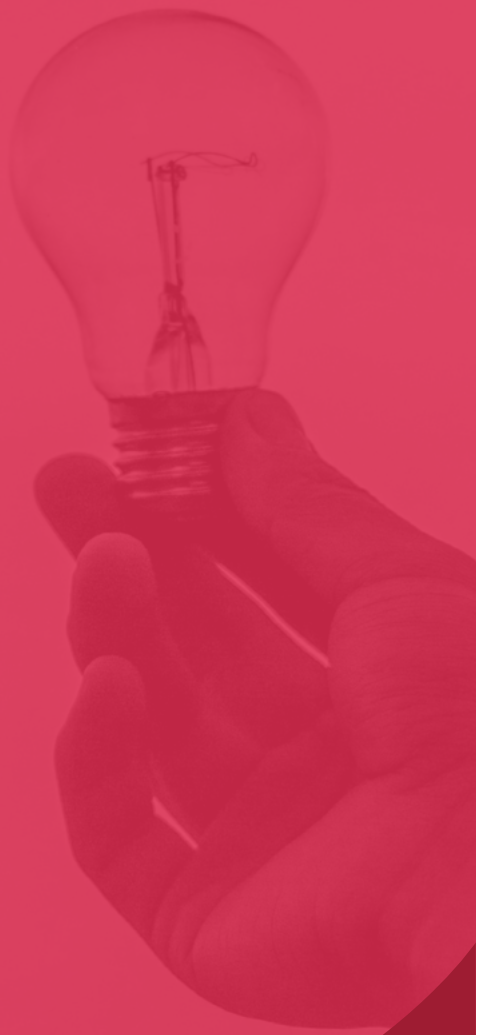
as well as a sizeable group of FDA regulations, including

- 21 CFR §11, FDA Electronic Records; Electronic Signatures;
- 21 CFR §50, FDA Protection of Human Subjects;
- 21 CFR §801, FDA Labeling;
- 21 CFR §803, FDA Medical Device Reporting;
- 21 CFR §806, FDA Medical Device Corrections and Removals;
- 21 CFR §810, FDA Medical Device Recall Authority;
- 21 CFR §820, FDA Quality System Regulation (QSR);
- 21 CFR §830, FDA Unique Device Identification;

together with data privacy and protected health information management, such as

- ISO/IEC 27001 — Information security management;
- Health Insurance Portability and Accountability Act of 1996.

RESOURCES



Our team of experts includes company veterans as well as fresh talent with a range of backgrounds, all of them continuously honing their skills through trainings, visiting relevant industry events and self-education. We have team members versed in every aspect of our process from client success management through auditing to technical writing, all the while making use of our curated set of procedure templates, a modern eQMS tool and proficiency in the standard office and task management applications. During our past operations we have also worked with dozens of external collaborators whose expertise remained available even after completing our cooperation.

CLIENTELE

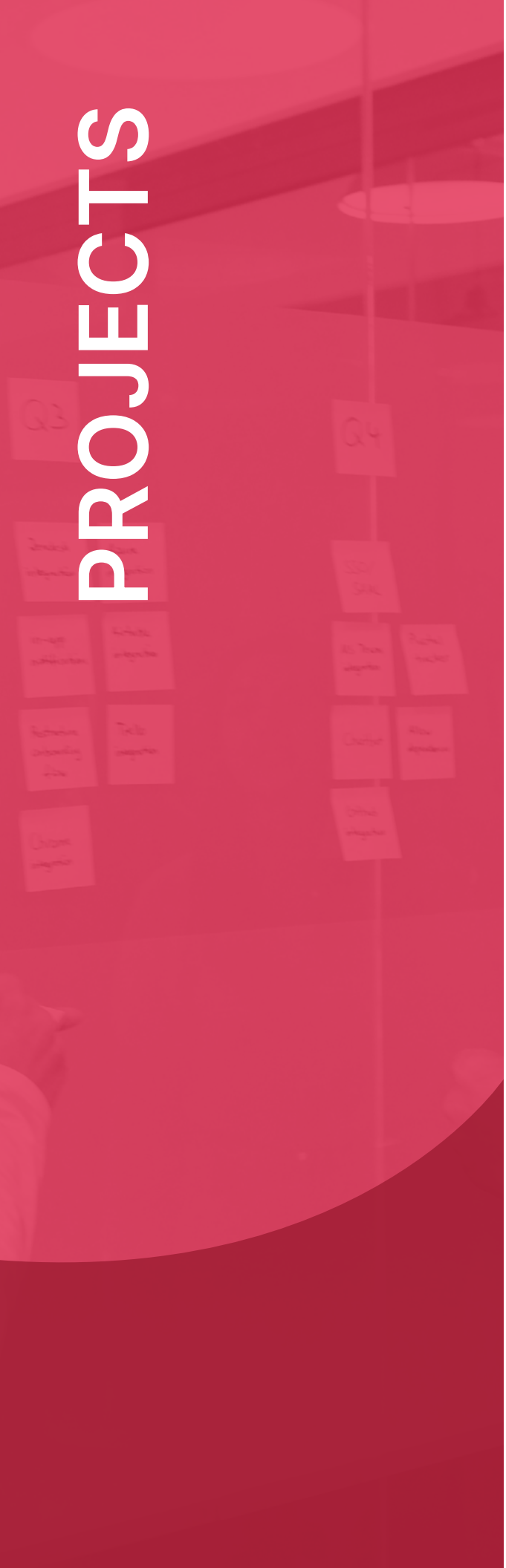
Previous projects in the realm of quality and regulatory compliance gave us the push to dedicate focus to existing and prospective clients needing assistance with their own product documentation. We have worked with a number partners ranging from one-man operations to multinational firms with customers on 4 continents, and ended up drawing the same conclusion: outsourcing QA activities works.

It saves time because of the pre-packaged solutions ready to be customized and implemented.

It saves risk through the new type of expertise that is introduced to the project.

Its biggest advantage though, compared to in-house solutions, is the very fact that just like auditors and assessors from certifying bodies, consultants are external to the product and the production team. This similarity gives them the same perspective, requires the same level understanding and provides the fresh set of eyes meant to identify gaps, irregularities, or improvement opportunities.

One of our proudest moments came from the simple-sounding accomplishment of completing a 510k submission for the notoriously scrupulous FDA under 80 days on first attempt. It is vital to reduce the number of re-submissions to as low as possible, because every round delays the product's release by up to 90 days, thus holding up marketability stopping the product from serving its intended users and not unimportantly making money for its owner.



PROJECTS

Past experiences and present market research together paved the way to our current project portfolio and the type of problems we aim to solve for our customers. The major categories for these projects are:

• Supporting software development projects with quality assurance specific activities, such as assuring compliant deliverables following the applicable procedures, giving advice on process optimization or reviewing ongoing production records.

• Providing consultancy on FDA and MDR compliant software development methods to med-tech start-ups with no bandwidth to build up an in-house quality and regulatory team.

• Analyzing existing deliverable packages prior to submission, identifying gaps, advising on documentation refinement in order to complete a quick evaluation process.

• Preparing previously certified products' supporting documentation for re-submission either due to significant changes to the product itself or to keep them compliant with updated regulations.

CONCLUSION

Every collaboration is a unique combination of product complexity, client experience, time constraint and current industry trends. While there are common goals, familiar requirements and proven paths to bring a project to success, we find challenge, as much as motivation, in figuring out the best way we can serve our clients. It is crucial to understand not only their product but the problem it was meant to solve, the audience it is targeting, and the ways it is going to be used, because only then will we be able to give useful advice.

Mitigating risks, meeting quality requirements and keeping deadlines is just a part of the picture though – customer satisfaction is impossible without building a professional relationship that is meant to last. When cooperation is based on reliability, openness as much as technical proficiency, it becomes a journey free of unexpected setbacks and ultimately, dissatisfaction. We understand that there are people behind the responsibilities, personalities behind the decisions and it is our mission to consider them as well as the tangibles of the project itself.

Because that is the IronRooster Way.