



AHMED Project

Final seminar

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WP1: Software Engineering & associated tool support

Research question

We aim to recognize opportunities for improvement and automatization in Medical Device Design and Development design processes for accelerated market entry, thus fulfil the regulatory requirements. We aim to call into question how IEC 62304 (Software Development Lifecycle) fits to current IVD, MD-Regulation and what are the possible bottlenecks when the Agile development paradigm is introduced.

WP1: Software Engineering & associated tool support

We evaluated our software development methodology against the regulation requirements and after gap analysis we decided to restructure QMS -especially the software development process was refined.

- Process structure were built on IEC 62304, ISO 13485 and IVDR requirements
- SOP:s and WI:s were written and matched on standards for better compliance
- Process artefacts are checked against standards and regulation
- We implemented SAFe

-after these adjustments we were ready for standardized Agility and DevOps-

WP2: Data Engineering & associated tool support

Research question

How to manage change control of algorithms, user developed scripts and configuration alteration in consideration of regulation.

How to extract information from patient treatment data and further refine it with algorithms for customer and patient benefit in decision making, furthermore, to get clear understanding what are regulatory constraints and classifications within IVDR/MDR for those properties.

WP2: Data Engineering & associated tool support

- Change control is a key issue in medical device development, especially for software
- Significant changes are hard for manufacturer who's products are still under IVDD
- We decided to isolate the medical device functions as a module and make sure that no significant changes are made to systems
- We don't own the data we handle, and customers do have their own data lake, data warehouse systems, because of that we withdraw from further algorithm and data analysis work.

WP3: Legal and regulatory aspects definition

Analysis of regulatory requirements with respect to risk management and mitigation, verification and validation, and traceability in the context of DevOps and continuous software engineering

WP3: Legal and regulatory aspects definition

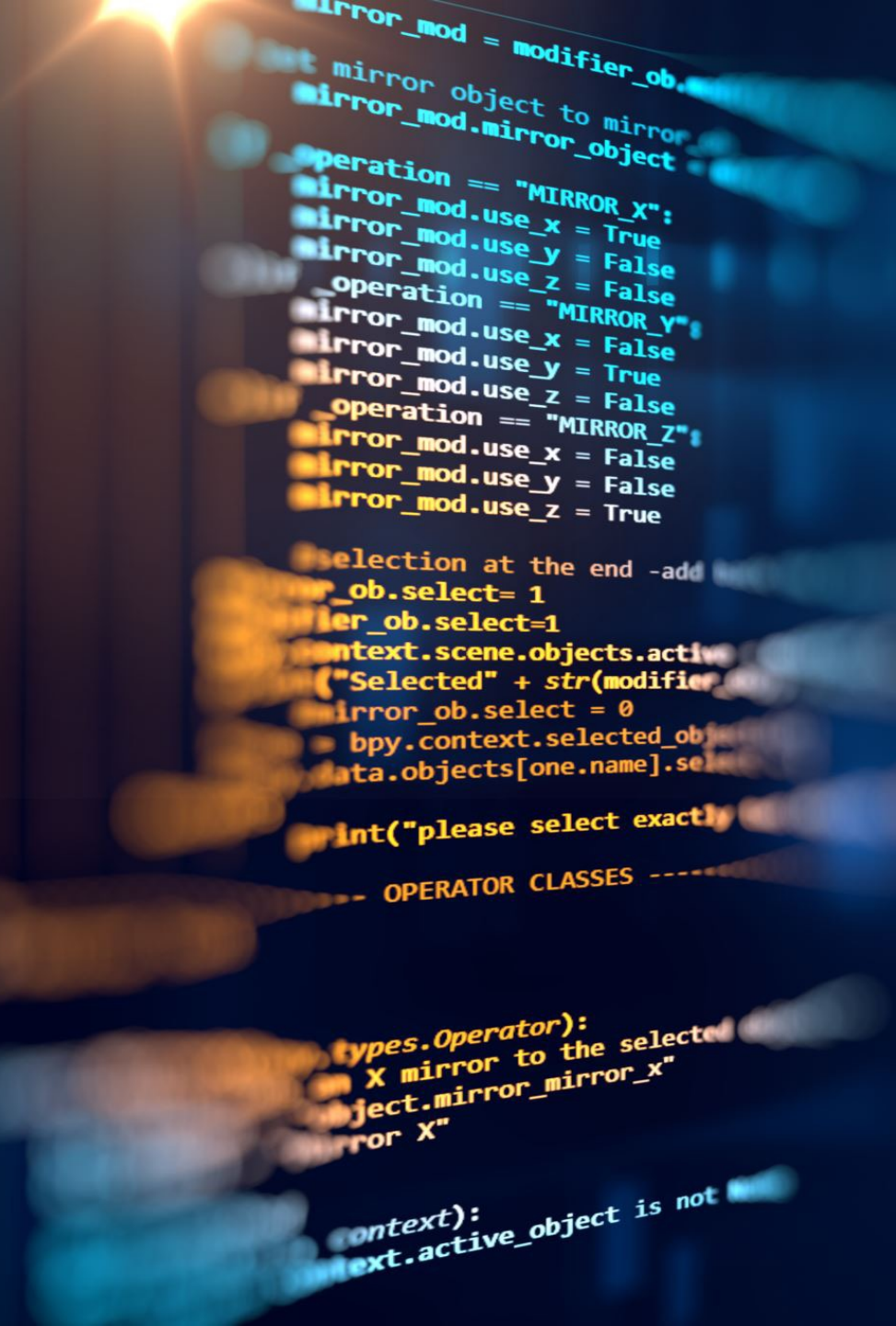
We made regulatory plans for our products

- Plans helped us to focus on regulatory critical components and gave some more freedom to act with others
- Risk assessments are focusing on safety, security and business risks

We also made recheck on IEC 62305 safety class assesment to prioritize refactoring efforts

After these tasks we have data for proper risk asesments in DevOps.

The DevOps tools should be validated as well as scripts, recipes and other artefacts they produce or rely on.



WP 4: End to End tooling for regulated devops

Research question

How to take full advantage of Risk Management and amend software development processes in a fast and efficient manner. How to opt Risk Management data not only for regulatory use but to improve Continuous Development and Company efficacy.

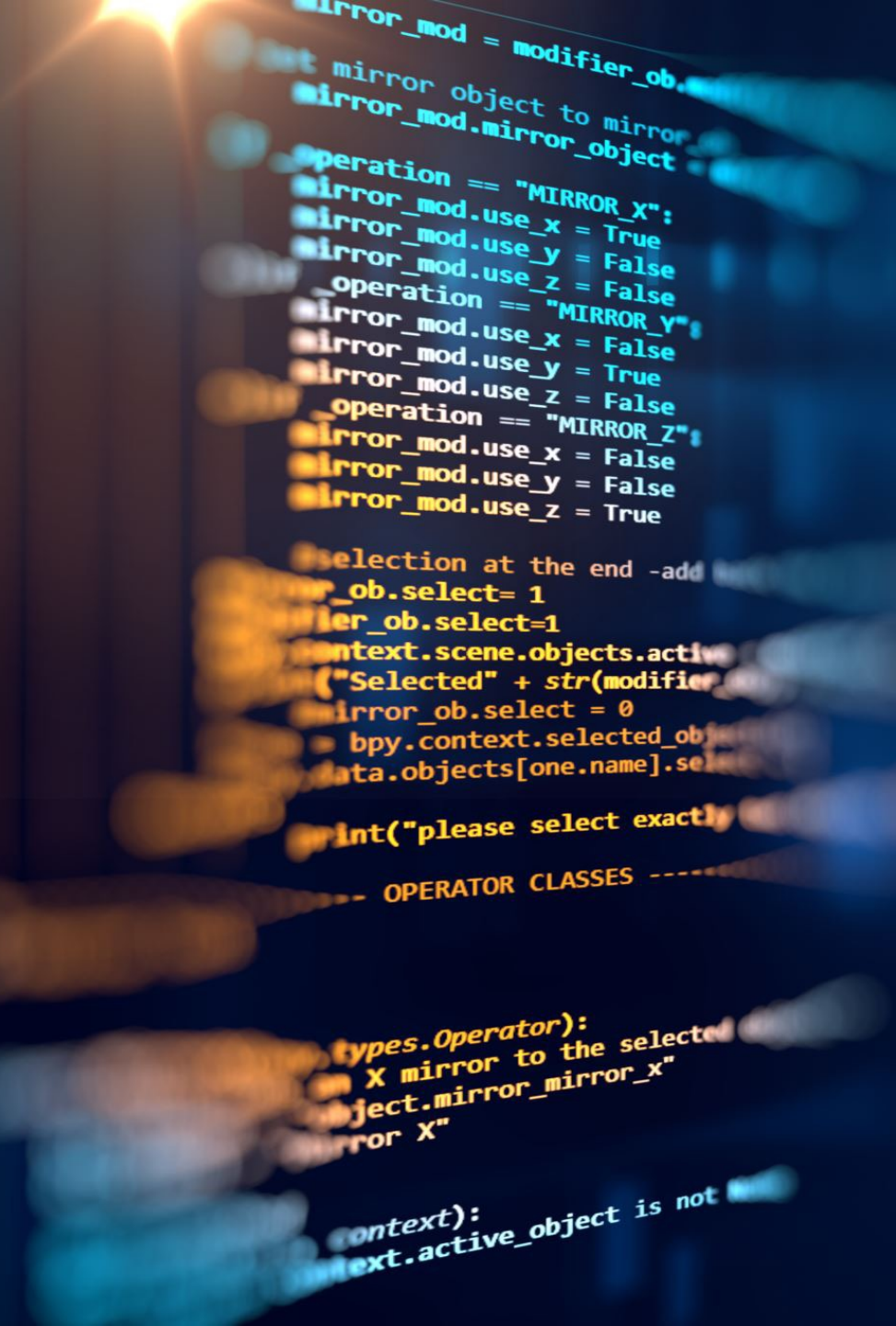
How to continuously evaluate risk management processes and adjust the thresholds.

WP 4: End to End tooling for regulated devops

We have adopted several DevOps tools for product lifecycle management

- Planning/Documenting/Coding/Risk management: Confluence/Jira,
- Gradle for build automation
- Jenkins for test automation
- Ansible for configuration management
- Nexus for artifacts
- Gitlab for version control
- Kubernetes for container orchestration
- Helm Charts for managing Kubernetes
- Argo cd for Deploy

Adjusting, optimizing, testing, mitigating risks and validating these tools is a continuous process



Thank you!

Questions?

We would like to thank Business Finland for funding this project