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Compliant Library Preparation for DNA Sequencing

A demonstration of how no-code technology can be used to provide overarching compliance for complex laboratory SOP’s such as DNA sequencing.

Contact us: okuda@maly.co.uk

Compliant Library Preparation

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Laboratory research science businesses and the lab managers that work for them face a significant challenge ensuring their labs meet stringent regulatory standards. They need to apply strict Standard Operating Procedures (SOP's) consistently across thousands of samples and experiments on a daily basis, and have high confidence that lab work does not deviate from SOP. This is especially true when their work is clinical in nature and has the potential to directly impact patients.

Tough compliance questions for lab managers…

- How do I ensure complex and time critical SOPs are applied and adhered to systematically every time they are undertaken by anyone working in the lab?
- How do I work with my IT team to ensure SOP's are integrated into the existing systems and processes of the lab to ensure seamless and efficient lab operation?
- How do I track every SOP instance and capture all interactions and data to enable later review and auditing by our quality control team?
- How do I demonstrate to regulatory bodies that we are compliant at all times across SOP's and be able to prove and back that up when challenged?

Lab protocol management and sample tracking through a no-code digital solution helps achieve rapid compliance for complex SOP's

If SOP's are not followed and proper compliance is not consistently implemented the impact for research science companies can ultimately be severe, particularly in clinical scenarios.

Non-compliance impacts:

- Potential loss of life or delay of treatment to a patient
- Mistakes with data control leading to patient data or IP leakage
- Invalidation of research studies and papers
- Inadvertent academic misconduct
- Investigations and audits consuming significant internal time and resource
- Significant reputational damage amongst the community
- Massive fines (e.g. consumer law breach - potentially up to 10% of global turnover)
- Loss of regulatory credentials and ability to trade and operate – loss of livelihood

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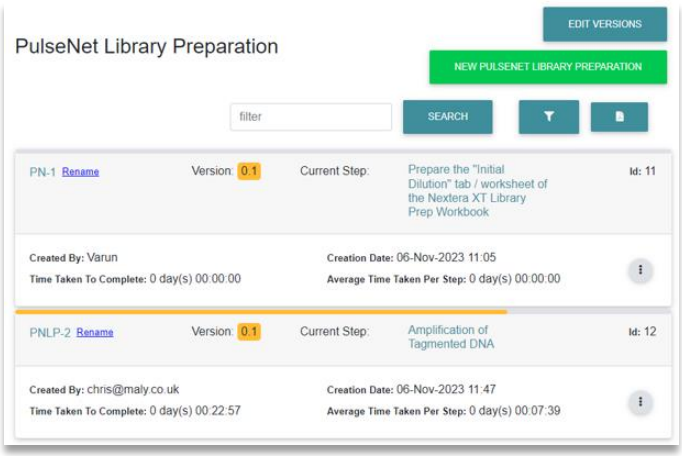

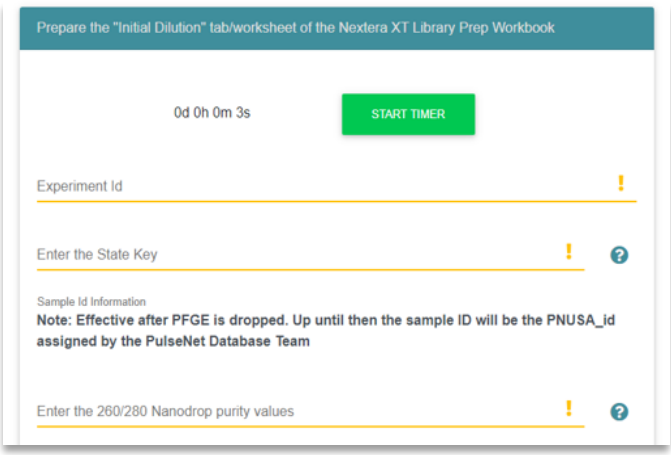

Our demonstration shows how a compliance management framework can rapidly be put in place to ensure lab operations meet the robust clinical standards required by the FDA, MHRA, or any other regulatory body. We have modelled the reference PulseNet (CDC) protocol for Illumina Nextera XT Library Preparation.

Based on the Okuda no-code process management platform our solution allows for rapid digitisation and deployment of SOP's ensuring the consistent repeatability of sampling processes. This is especially important for clinical environments where outcomes are directly patient impacting.

- For this demonstration we have shown how Okuda can digitize a CDC-published library preparation protocol for genomic sequencing – a particularly long, complex laboratory process spanning many time critical steps.
- This paradigm of protocol development/digitised SOP can supplement or enhance any existing QMS (Quality Management System) by providing overarching compliance management that integrates with other applications and systems such as e-signature sign offs, billing or CRM, or equipment maintenance.
- It can also provide operational-level reports of turn-around times and on-the-fly upkeep of documentation and maintenance of compliance certifications.

Benefits

- Digitise and automate complex SOP's and integrate them with existing lab applications, systems and equipment
- Ensure consistent application of SOP's by everyone at all times
- All interactions and data captured for later review, audit and analysis
- Visual dashboards allow operational level views on cycle times and other lab performance parameters
- Quickly adopt and implement any changes to the SOP
- Automated production and up-keep of documentation
- Maintenance of compliance certifications

The Okuda Platform

The Okuda technology platform is designed for creating, implementing, operating and monitoring regulatory compliance processes across organisational silos. Acting as a "compliance control room" it gives real time visibility of process progress enabling pro-active prevention of non-compliant incidents. The platform is supported by the Maly experts who will work with you to design, deploy and operate your customised solution.

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