ASTELLAS IRELAND (KP)

Skillnet Innovation Exchange
13th November 2024

ASTELLAS KERRY PLANT

AICL KERRY PLANT LOCATION

.45 Minutes

3.5 Hours

3.2 Hours

PRODUCTS MANUFACTURED / PACKAGED AT AICL KERRY PLANT

PRODUCT	STRENGTH	PACKAGING	MARKETS
Prograf™ Tacrolimus — Tacrolimus Capsules, hard	0.5mg, 1mg and 5mg	Blister Packs	Global markets
	0.5mg, 1mg and 5mg	Bottle Packs	United States, Canada, HIKMA
ADVAGRAF™ tacrolimus prolonged release — Tacrolimus Prolonged-release Capsule, Hard	0.5mg, 1mg, 3mg, 5mg	Blister Packs	Global markets
	0.5mg, 1mg, 5mg	Bottle Packs	United States
Prograf™ Tacrolimus — Tacrolimus Concentrate for Solution for Infusion	5mg/ml	Glass Ampoules	Global Market
	2mg/amp	Glass Ampoules	Japan
Modigraf™ tacrolimus granules — Tacrolimus Granules for Oral Suspension *(Importation Secondary packaging, QP release)*	0.2mg, 1.0mg	Sachets	EU, Switzerland
MYCAMINE® (micafungin sodium) for injection — Micafungin sodium Powder for Solution for Infusion *(Importation Secondary packaging, QP release)*	50mg,100mg	Vials	EU, Switzerland, Serbia, Israel, Africa, Russia & CIS
PADCEV™ enfortumab vedotin Injection for IV infusion 20 mg & 30 mg vials — Enfortumab Vedotin* Lyophilized Powder for Solution (Importation Secondary packaging, QP release)	20mg, 30mg	Vials	EU, Israel, Switzerland, Singapore & UK.

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PRODUCTS MANUFACTURED/PACKAGED AT AICL KERRY PLANT

PROCESSING/ PACKAGING LINE	PRODUCT(S) PROCESSED/ PACKAGED
Ampoule Compounding Area, Filling & Packaging	Compounding, Aseptic Filtration & Filling, Integrity Testing, Inspection and Packaging of Prograf Ampoules
Two Capsule Powder Blending Suites Four Capsule Filling Lines	Formulation and Filling of Prograf and Advagraf Capsules
Three Blister Packaging Lines	Packaging of Prograf and Advagraf Capsules
One Bottle line	Packaging of Prograf and Astagraf Capsules
Vial/Sachet Packaging Area	Secondary Packaging of Mycamine and Modigraf
Biologics Packaging Line	Secondary packaging of Padcev Vials

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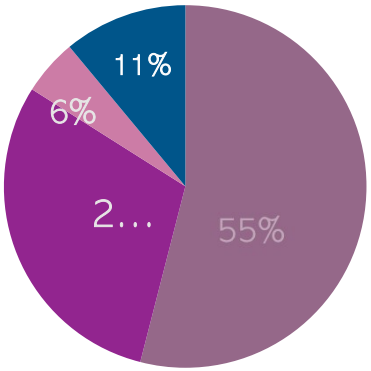
HUMAN RESOURCES

AREA	No. of Employees	Permanent	Temporary
Production & Warehouse	219	203	16
Quality (QA & QC)	112	93	19
Engineering (incl EHS)	22	20	2
Senior Management, Finance, Global & Admin	42	37	5
Total	395	353	42

DEPARTMENTS

- Production, Warehouse & Supply Chain
- Quality (QA & QC)
- Engineering (inc EHS)
- Senior Management, Finance, Global & Admin



395
Employees

90%
3rd Level Education

51%
Degree
Masters
PHD

MANAGEMENT OF OBSOLESCENCE IN AICL(KP)

Problem Statement & Request for Expertise

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BACKGROUND

In our rapidly evolving pharmaceutical manufacturing facility in Killorglin, managing obsolescence has become a challenge. Key equipment, systems, and technology are aging; leading to downtime, maintenance issues, and potential risks of non-compliance.

KEY CHALLENGES

- Aging Equipment & Machinery
- Outdated Control Systems & Software
- Compliance & Regulatory Risk
- Increased Maintenance & Downtime
- Limited Vendor Support
- Knowledge Transfer Gap
- Cyber Security

Impact on Operations

Obsolescence issues are significantly affecting our operations:

Increased Downtime: Frequent production stoppages due to sourcing delays for obsolete parts.

Escalating Costs: Unplanned procurement and emergency repairs are inflating operational expenses.

Production Risks: Unpredictable equipment failures jeopardies our ability to meet production timelines & risk to stable supply.

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REQUEST FOR SOLUTIONS

We are seeking a comprehensive and proactive approach to managing obsolescence, including:

Obsolescence Risk Assessment: Evaluating current and future risks to minimise disruptions.

Lifecycle Management: Strategising replacements and upgrades for obsolete equipment.

Supply Chain Solutions: Ensuring availability of critical parts through alternative suppliers or redesigns.

Preventive Maintenance Programs: Implementing measures to prevent breakdowns and extend equipment life.

AUTOMATED DOCUMENTATION MANAGEMENT

Problem Statement & Request for Expertise

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BACKGROUND

We spend disproportionate time on repetitive documentation tasks, including generating, reviewing, and rewording content based on subjective feedback – which can cause frustration & diverts focus from core tasks, increase project time-lines, and risks inconsistencies and compliance issues. We need a solution to automate and standardise documentation process, enhancing productivity and quality across projects.

KEY CHALLENGES

- Time-Consuming Documentation Tasks
- Subjective Rewording
- Risk of Inconsistencies
- Limited Reusability & Standardisation
- Review done on Post-its

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Impact on Operations

Reduced Productivity: Engineers spend excessive time on documentation tasks, limiting their capacity for core technical work and slowing overall project progress.

Project Delays: Repeated documentation reviews and subjective rewording extend timelines, creating bottlenecks in project delivery.

Repetitive Errors and Limited Learning: Errors are often repeated, and lessons from previous projects or documents aren't systematically captured or applied to improve future documentation.

Team Frustration and Morale Impact: Repetitive, non-technical tasks and subjective rewording cause frustration, impacting team morale and engagement

REQUEST FOR SOLUTIONS

We are seeking an AI-driven or automated solution to streamline our documentation processes and address the following needs:

Automated Document Generation:
Tools to quickly create project/ validation-specific documentation based on reusable templates, reducing manual effort.

Error Reduction and Learning Integration:

Solutions that capture and apply learnings from previous projects to prevent repetitive errors and improve document quality.

Standardised Language and Style:
Natural language processing (NLP) capabilities to maintain consistency and reduce subjective rewording.

Compliance and Quality Assurance:

Built-in validation features to ensure documentation aligns with compliance standards and is free of inconsistencies.

REQUEST FOR EXPERTISE

We invite SME's/ Consultants/ Start-ups with experience in pharmaceutical manufacturing to submit a proposal. Key focus: innovation, regulatory compliance, operational efficiency.