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Abstract

The limited internal utilization of a portable passivation skid in a biopharmaceutical manufacturing facility resulted in reliance on outsourced passivation services, increasing operating costs. This project applied a structured Define – Measure – Analyze – Improve – Control methodology to quantify the economic and operational impact of contractor executed passivation and to evaluate internal execution alternatives within a three-month project window. Baseline analysis demonstrated that contractor executed passivation events incurred significantly higher costs than internally executed activities, even when internal support labor was considered. Cost–benefit evaluation by passivation type identified recurring heat exchangers and a 500-liter tank as high impact candidates for internal execution. Results showed that internal passivation reduced per event costs by approximately 80% for the heat exchangers and by more than 70% for the tank. The primary constraint limiting internal passivation was economic dependence on external contractors rather than technical capability.

Introduction

Context - A biopharmaceutical API facility performs passivation of stainless-steel equipment to restore the chromium-rich passive layer that protects against corrosion and contamination after major interventions.

Problem - Although a portable passivation skid with automation and safety features was available, it was underutilized due to mobility limitations, assembly complexity, and lack of standardized automated sequences. The facility relied on an external contractor to perform passivation activities. This resulted in higher costs, longer downtime, and reliance on external contractors for routine passivation.

Project Objective - Increase routine internal use of the portable passivation skid to improve cost efficiency, operational readiness, and long-term equipment integrity by addressing technical, process, and operational constraints.

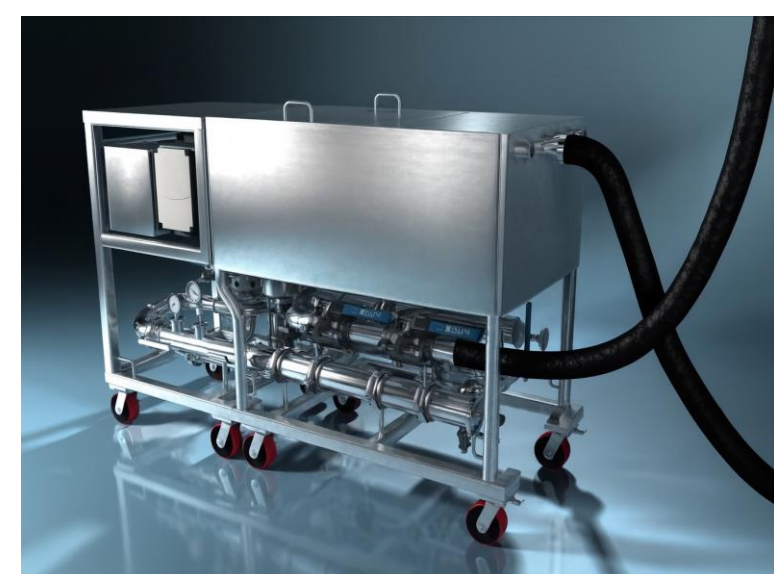


Figure 1
Example Portable Passivation Skid

Literature Review

Passivation Fundamentals - Effective passivation requires maintaining the chromium-rich passive layer that provides corrosion resistance in stainless steel. Its stability is influenced by surface condition, temperature, chemical exposure, and flow dynamics; deviations increase susceptibility to pitting, crevice corrosion, and generalized attack [1]



Source: Abfad, "Pitting Corrosion and Storage Tank Failure" <https://www.abfad.co.uk/editorial/pitting-corrosion-and-storage-tank-failure/>

Figure 2
Pitting Corrosion Examples

Role of Automation - Surface conditioning benefits from defined operating parameters and repeatable flow conditions. Automated skids support consistent execution by controlling sequence, temperature, flow rate, and contact time, while excessive manual intervention increases variability and may reduce passivation effectiveness [1], [2].

Literature Review cont.

Operational & Ergonomic Constraints - Industrial ergonomics literature indicates that pushing, pulling, and aligning portable equipment can increase physical strain and handling risk, particularly in constrained spaces. Limited maneuverability can discourage routine internal deployment of portable systems [3].

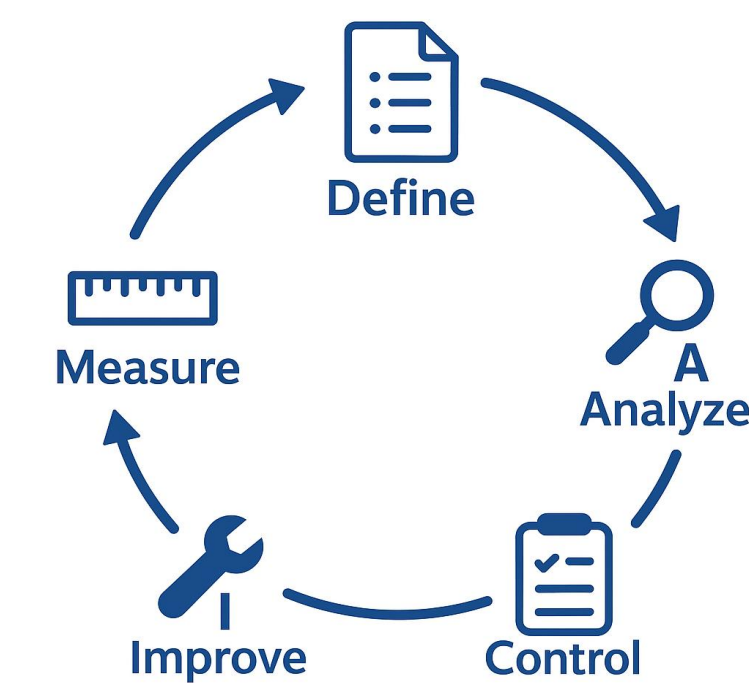
Quality & Process Consistency - Effective passivation depends on complete circulation, uninterrupted flow, and sufficient contact time, not solely on chemical concentration [1], [4]. Quality-control principles associate predictable outcomes with standardized processes and reduced operator dependency, supporting automation and internal capability development [5].



Figure 3
Before and after tank passivation

Analysis Approach

A DMAIC (Define–Measure–Analyze–Improve–Control) methodology was applied to evaluate limitations affecting internal utilization of the portable passivation skid and to implement sustainable improvements within a three-month project window.



Define

- Documented current skid deployment, movement paths, setup steps, and passivation requirements
- Collected operator, maintenance, and SME input on ergonomic constraints and outsourcing drivers
- Outputs: clear problem statement, validated user needs, and focused project scope

Measure

- Established baseline performance using:
 - Frequency, duration, and cost of outsourced passivation
 - Skid relocation, assembly time, and labor
 - Manual steps per passivation cycle
 - Ergonomic observations and physical clearance measurements
- Hose management and staging activities were excluded from scope

Analyze

- Identified key limiting factors:
 - Mobility and footprint constraints
 - Assembly complexity
 - Execution variability due to manual intervention
 - Behavioral and historical reliance on outsourcing

Improve

- Implemented targeted enhancements:
 - Mobility and ergonomic aids
 - Visual setup guidance and workflow simplification
 - Automated recipes for routine preventive maintenance passivation of selected equipment
- Engineering runs and validated simulations were used to verify reductions in manual effort, setup time, and variability

Control

- Sustained improvements through:
 - Updates to PM job plans, procedures, and recipe documentation
 - Operator and maintenance training
 - Monitoring via Maximo for utilization trends and outsourcing reduction
- Deliverables integrated into site quality and maintenance systems

Results

Application of the DMAIC methodology resulted in measurable economic and operational improvements by increasing internal execution of passivation activities using the portable skid. Cost and operational dependence on contractor-executed passivation were compared against internally executed activities for representative equipment.

As shown in Figure 4 and detailed in Tables 1 and 2, contractor-executed passivation resulted in substantially higher costs per event. For heat exchangers, contractor execution averaged approximately \$22,500 per event, compared to \$4,800 for internal execution. For the 500-liter tank, contractor execution averaged approximately \$7,000 per event, compared to \$2,100 internally. Contractor service fees represented the primary driver of the higher total cost.

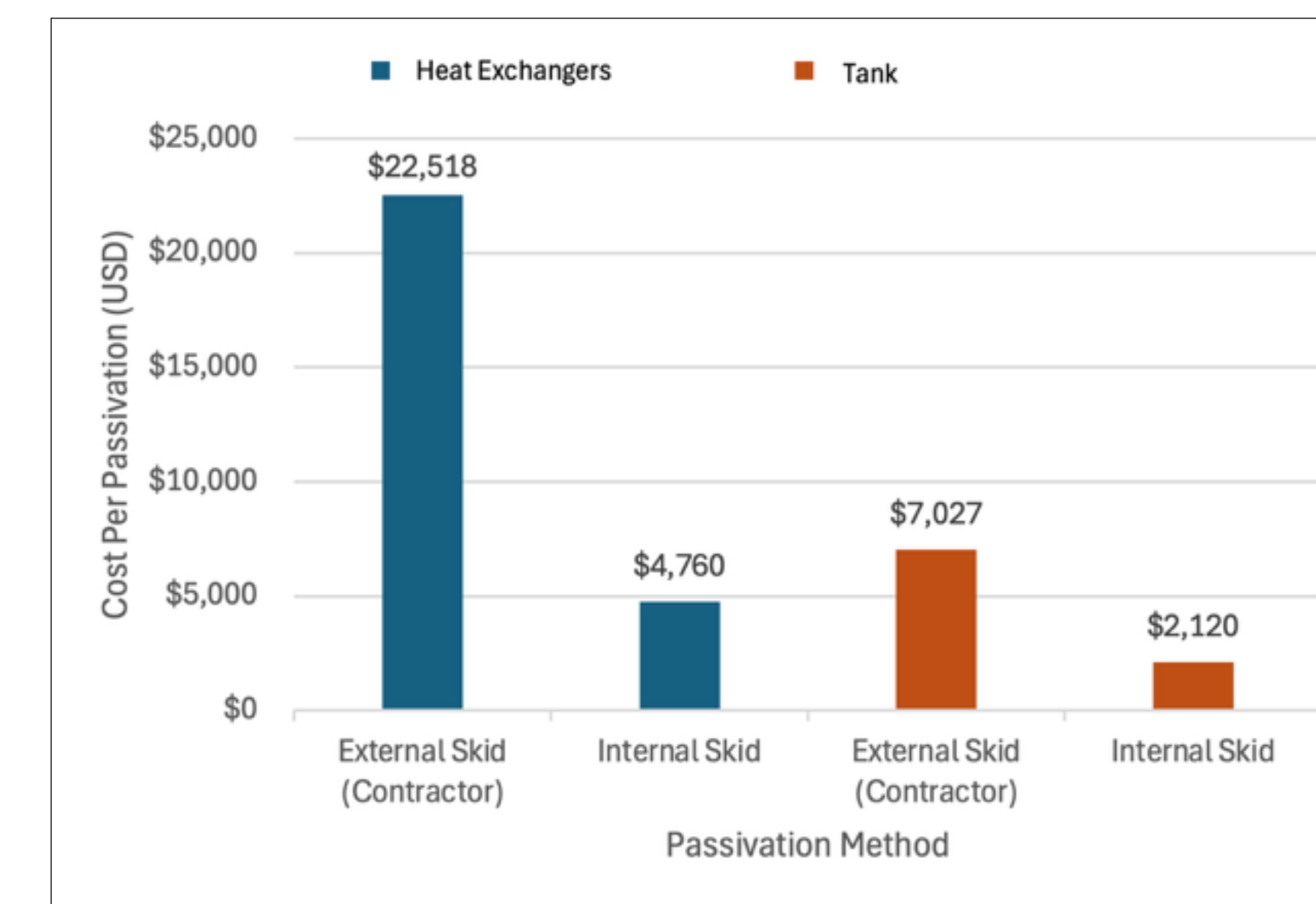


Figure 4
Baseline Cost Comparison per Passivation Event

Cost Element	External Skid (Contractor)	Internal Skid
Contractor Labor Hours	156 hrs	-
Internal Labor Hours	48 hrs	72 hrs
Internal Labor Cost (\$55/hr)	\$2640	\$3960
Materials/chemicals	Included	~\$800
Contractor Service Cost	\$19,978	-
Cost per Passivation	\$22,518	\$4,760

Table 1
Heat Exchanger Cost Comparison per Passivation Event

Cost Element	External Skid (Contractor)	Internal Skid
Contractor Labor Hours	48 hrs	-
Internal Labor Hours	16 hrs	24 hrs
Internal Labor Cost (\$55/hr)	\$880	\$1320
Materials/chemicals	Included	~\$800
Contractor Service Cost	\$6,147	-
Cost per Passivation	\$7,027	\$2,120

Table 2
Tank Cost Comparison per Passivation Event

When annualized, contractor execution for five heat exchangers resulted in an estimated cost of approximately \$112,600 per year, while internal execution reduced this to approximately \$23,800, corresponding to an ~80% cost reduction. Passivation of the 500-liter tank resulted in an additional ~70% cost reduction, equivalent to approximately \$5,000 in annual savings.

Operational feasibility assessment confirmed that internal execution was achievable when predefined transport routes and deployment locations were used. Deployment limitations were attributed to the absence of standardized route planning rather than equipment size or weight. Standardized automated passivation recipes further reduced manual intervention and improved execution consistency.

Conclusions

This project demonstrated that the limited internal utilization of the portable passivation skid was driven primarily by economic and operational dependence on external contractors rather than by technical limitations of the equipment. Through the application of the Define–Measure–Analyze–Improve–Control methodology, this dependence was systematically evaluated, quantified, and addressed within a constrained three-month project window.

The results confirmed that internal execution of routine passivation activities provides significant economic advantages when compared to contractor-based execution. Baseline cost analysis showed that contractor service fees represented the dominant contributor to total passivation cost, even when internal support labor was required. By selecting high-impact passivation activities and executing them internally, substantial cost reductions were achieved, as demonstrated by the annualized heat exchanger and 500-liters tank case studies.

From an engineering management perspective, this project highlights the importance of data-driven decision-making and targeted optimization rather than broad process redesign. Prioritizing passivation activities based on cost–benefit impact enabled effective allocation of internal resources while reducing reliance on external services. Increasing internal passivation capability strengthens operational control, improves cost efficiency, and supports long-term sustainability of maintenance practices. The approach developed in this project can be applied to evaluate additional equipment for internal passivation based on measurable cost impact and operational relevance.



Future Work

Future work will focus on expanding and sustaining the internal passivation capability established in this project.

- **Expansion of automated recipes** to additional equipment types and passivation applications to further reduce contractor dependency.
- **Standardization of deployment planning**, including formal route maps and designated utility-ready deployment locations across additional production areas.
- **Evaluation of additional ergonomic and mobility enhancements** to further simplify deployment and reduce physical handling demands.

References

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- [5] D. C. Montgomery, Introduction to Statistical Quality Control, 8th ed. Hoboken, NJ, USA: Wiley, 2021.