Manufacturing Outsource Process

Your Template For Success

Delivering Innovative Medical Technologies
Objective:
Understand objectives and requirements, review alternative solutions and develop proposal for recommended solution.

Deliverables:
- Project scope and definition
- Review of alternative options
- Proposal based on recommended option
- Agreement to move to next stage

Objective:
Develop detailed project plan.

Deliverables:
- Project teams in place
- Project communications, review and management processes in place
- Full due diligence complete on all aspects of the project
- Detailed project plan developed
- Major risks identified and risk management plan in place
- Agreement on detailed plan including scope, schedule and budget

Objective:
Complete product development, including testing as per customer criteria.

Deliverables:
- Product changes/ enhancements proven to meet customer requirements
- All required integration or functional testing complete at customer site
Objective: Transfer all available equipment and tooling and purchase remaining equipment & tooling. Set up manufacturing lines and IQ all equipment.

Deliverables:
- Manufacturing lines set up and operational
- All IQs complete
- Staff hired and trained
- All required documents (procedures, drawings, specifications) approved and released for use

Objective: Execute all process validations (OQ/PQ) and product validations (PPQ) for finished devices.

Deliverables:
- All validations executed and reports approved
- MVR approved
- FAI complete

Objective: Ramp lines to full volume while ensuring yield and quality targets are met.

Deliverables:
- Manufacturing line capable of delivering target output and quality metrics
- Safety / consignment stock in place

Objective: Ongoing management of manufacturing operation with appropriate metrics and reviews in place.

Deliverables:
- QBR metrics and review process established
## Manufacturing Outsource Process Template

### Stage 1 - Project Feasibility
- Understand Customer Requirements
- Complete Technical Assessment
- Complete Financial Assessment
- Develop Outline Proposal
- Customer Review of Proposal
- Feasibility Stage Closeout Review

### Stage 2 - Detailed Planning
- Confirm Scope of Project
- Creganna Project Lead and Team Identified
- Steering Team and Review Process Agreed
- Customer Project Lead and Team Identified
- Define Project Management and Controls
- Risk Management Process Defined
- Develop Detailed Project Plan
- Review Budget and Product Pricing
- Supply Agreement Developed
- MVP Drafted and Approved
- Review and Agree Changes to Project
- Detailed Planning Stage Closeout Review

### Stage 3A - Development
- Complete Product Development as per Plan
- Test Product Development as per Customer Criteria
- Development Stage Closeout Review

### Stage 3B - Transfer / Install
- Purchase, Install & IQ Equipment & Tooling
- Facilities Set Up and Validation
- Hire and Train Staff
- Transfer, Install & IQ Equipment & Tooling
- Set up and Qualify New Suppliers
- Order Materials and Consumables
- Transfer and ECO all Documents and Specifications
- Draft Validation protocols
- Execute Test Method Validations
- Transfer / Install Stage Closeout Review

### Stage 4 - Validation
- Execute DOE’s and Engineering Studies
- Finalise and approve validation protocols
- Build and Test QO Lots
- Build and Test PQ Lots
- PQ Reports
- Complete Master Validation Report
- Complete FAL
- Notify Regulatory Agency
- Validation Stage Closeout Review

### Stage 5 - Manufacturing Ramp
- Line Audit for Manufacturing Start Up
- Confirm Ramp Plan and Metrics
- Build Safety / Consignment Stock
- Review Manufacturing Performance
- Manufacturing Stage Closeout Review

### Stage 6 - Ongoing Operations
- Agree Performance Metrics
- Set up Performance Review Process
- Manage Safety / Consignment Stock
- Project Closeout Review

### Summary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>MVP</td>
<td>Master Validation Plan</td>
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<tr>
<td>MVRS</td>
<td>Master Validation Report</td>
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<td>HI</td>
<td>Installation Qualification</td>
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<td>OQ</td>
<td>Operational Qualification</td>
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<td>PQI</td>
<td>Process Qualification</td>
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<td>Test Method Validation</td>
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<td>FH</td>
<td>Final Article Inspection</td>
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<td>ECO</td>
<td>Engineering Change Order</td>
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### Abbreviation List
- CREGANNA
- SERVICE
- NETWORK

Reduction your to market, cost and risk
Creganna is a leading supplier of products, technologies and services to medical device and lifescience companies. The company is ranked as one of the Top 10 global providers of medical device outsourcing solutions worldwide and has expertise in the design and manufacturing of minimally & less invasive delivery & access devices for a range of therapy areas.

The template inside outlines our approach to planning and execution of your outsource projects. Our staged process ensures a structured approach and stakeholder alignment with specific objectives and deliverables throughout the project.

For medical device companies seeking a manufacturing partner for products, sub-assemblies or component parts, Creganna offers an outsourced manufacturing service with the lowest risk and total cost of ownership. Our proven approach allows Creganna to function as a reliable outsourcing partner, for single manufacturing lines through to complete facility transfer. Creganna is fully compliant to industry standard ISO certification, is an FDA registered Contract Manufacturer and is registered with the Japanese MH&W as a foreign medical device manufacturer.