



A Contract Manufacturer's Perspective

Meeting FDA and OEM's Compliance Requirements

- 1 How Does a 1st Tier Supplier meet regulatory (FDA and other global regulatory agencies) requirements?
- 2 How does it meet its OEM customers requirements?
- 3 How does it assure risk mitigation and patient safety?
- 4 How does it manage its suppliers?

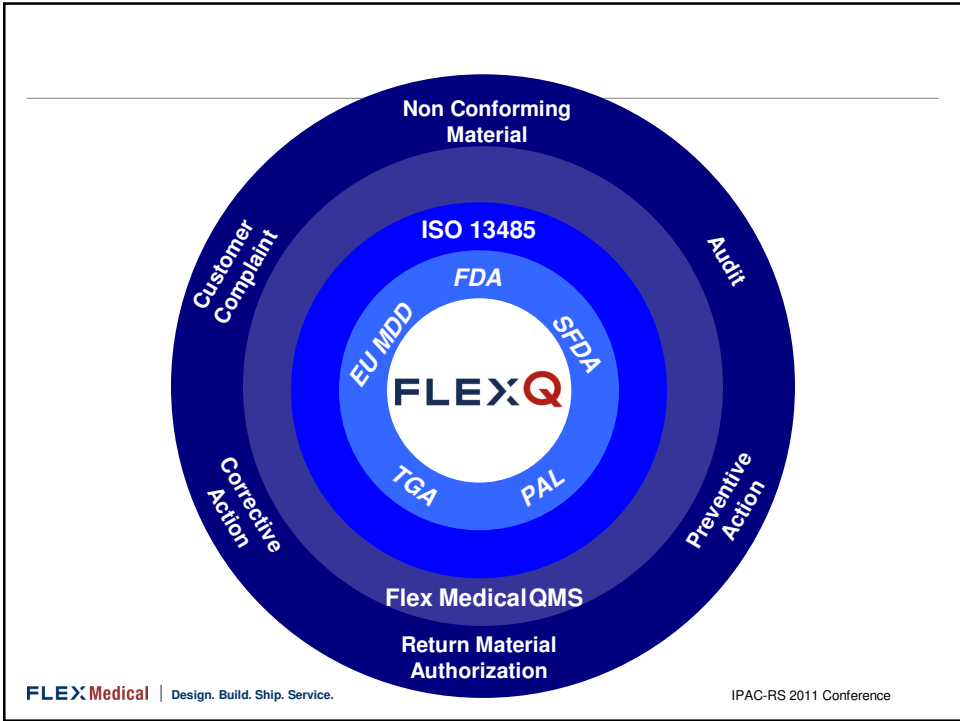
Centralized/Decentralized Global Quality Management Partnership and Manage all FDA Inspections

Lead	Core Centralized Corporate Quality Activities
Dir. QMS	Systems Development, including Electronic QMS Control System (FlexQ)
	Avail-Flex Systems Integration
	Quality Reports
	PLC Development
Directors Quality Engineering	Reliability Eng.
	Programs Support
	Site Specific Support
	Site Validation Support
Sr. Mgr. SQE	Supplier Management
	Compliance, Audits
Dir/Sr. Mgr. Regulatory Compliance	Site/Product Registration
	FDA Audit Management
	Deployment of QMS, Site ISO Audits, Training
	Software Validation and Change Management



Web-Based QMS, Part 11 compliant, passed multiple FDA Inspections: FlexQ Integration with Internal Applications





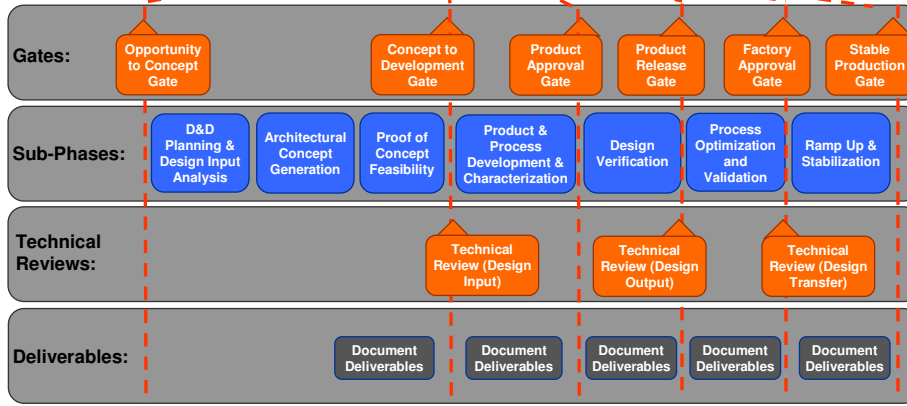
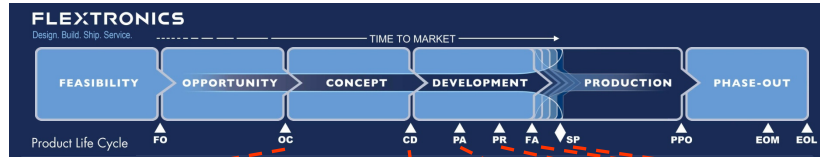
FLEX Medical

Meeting Customers (OEM) requirements

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IPAC-RS 2011 Conference

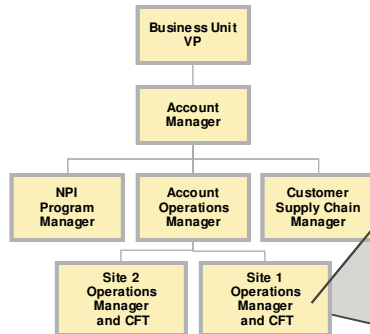
Company Defined Product Life Cycle



Customer Focus Team (CFT)

Account Management Team

A scalable Account Management Team is created to meet the needs of the account and to manage all customer projects globally

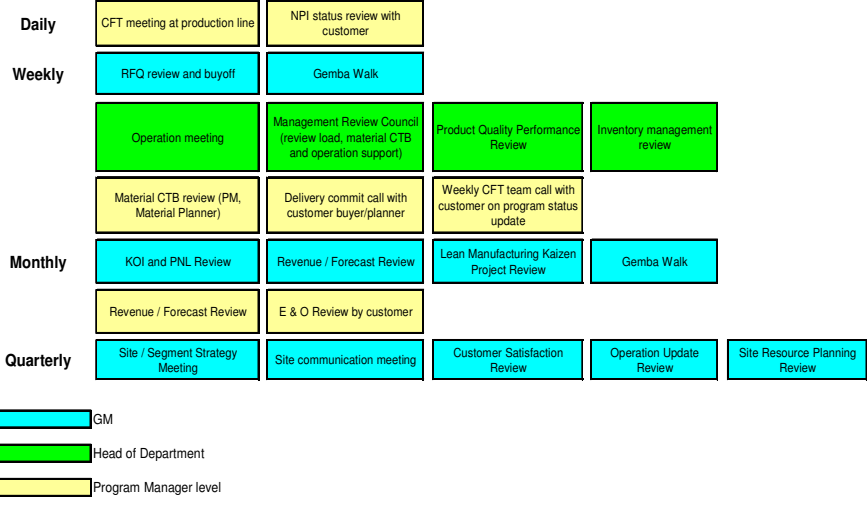


Customer Focus Team (CFT)

Provides cross-discipline linkage to all facets of project execution



Management Processes



Customer Satisfaction Measurement Survey (CSMP)

CSMP Survey Questions Workbook
The question sections below are mandatory for CSMP surveys. Optional sections are located on separate tabs.

FLEX:TRONICS Customer Satisfaction Measurement Survey

Date: _____
 Electronics Contact (Program/Project Manager): _____
 Electronics Facility Location: _____
 Customer Company Name: _____
 Division/Sub-Division (if applicable): _____
 Project/Program Name: _____
 Product Type: _____
 Customer Contact Name: _____
 Customer Contact eMail Address: _____

Rating Scale: 1 to 5
 1 - Unacceptable / Extremely Dissatisfied
 2 - Dissatisfied
 3 - Meets Expectation
 4 - Very Satisfied
 5 - Always Exceeds Expectation / Extremely Satisfied

Place an 'x' in the box to the right of the number which best represents your assessment of Electronics' performance.

Strategic Value (Do we add value?)

Electronics is aligned to meet your needs and creates value that increases your competitiveness. 1 2 3 4 5

Overall business processes and systems make it easy to conduct business with Electronics. (Example: NPV/PPCL/ ECO) 1 2 3 4 5

Overall communication and responsiveness is appropriate and matches customer expectation. 1 2 3 4 5

Quality (Do we have excellent quality?)

Demonstrates a commitment to continuous improvement. (e.g. Lean/Six Sigma) 1 2 3 4 5

Quality of products /services meets agreed targets. 1 2 3 4 5

Quality systems and tools enable prevention of, and rapid resolution to quality issues. 1 2 3 4 5

Cost Management (Are we competitive?)

Offering products and services at a competitive price. 1 2 3 4 5

Proactiveness of cost reduction efforts. 1 2 3 4 5

Delivery of Products and/or Services (Do we meet commitments?)

On Time Delivery (per commit) 1 2 3 4 5

Schedule flexibility (per agreement) 1 2 3 4 5

Proactive notification of schedule changes. 1 2 3 4 5

Supply chain architecture and performance leads to assurance of supply. 1 2 3 4 5

% deliveries late this quarter _____

% shipments incomplete this quarter _____

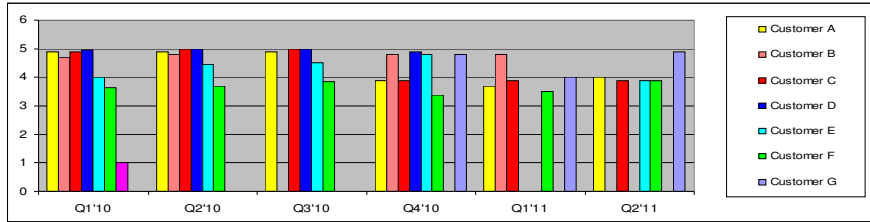
Overall Relationship (Use 5 Point Scale as to what degree). (Will we grow with them?)

Electronics overall performance compared to EMS competitors. 1 2 3 4 5

- Quarterly CSMP feedback from customer
- Flex to align customer expectation

Customer Satisfaction Trend Chart

Customer Satisfaction Measurement Program

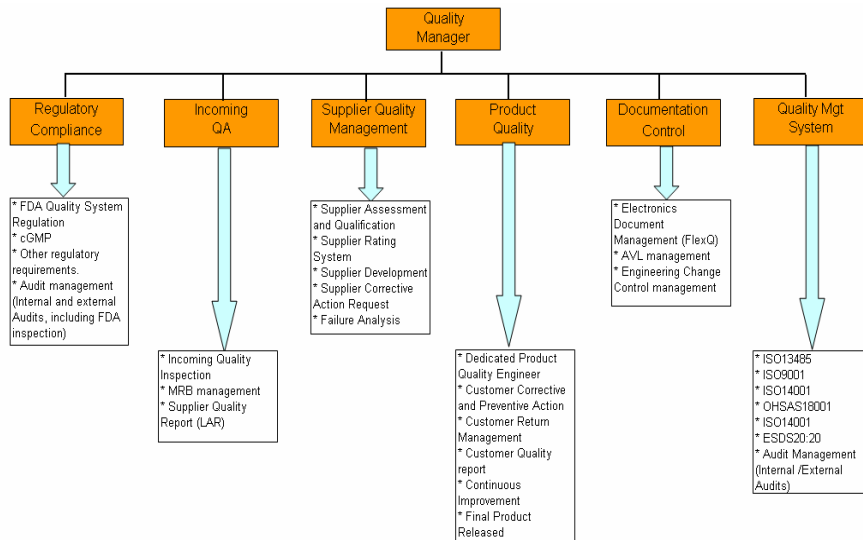


CSMP score summary

	Q1'10	Q2'10	Q3'10	Q4'10	Q1'11	Q2'11
Customer A	4.9	4.9	4.9	3.90	3.70	4.00
Customer B	4.71	4.81	0.0	4.80	4.80	0.00
Customer C	4.9	5.0	5.0	3.90	3.90	3.90
Customer D	4.95	5.0	5.0	4.90	0.00	0.00
Customer E	4.0	4.46	4.53	4.80	0.00	3.90
Customer F	3.62	3.69	3.85	3.38	3.50	3.90
Customer G	0.0	0.0	0.00	4.80	4.00	4.90
Average	4.5	4.0	4.7	4.4	4.0	4.1

- Full score for CSMP is 5. Score 3 is meeting customer expectation

Operations site Compliance and Quality Management



Alignment to recent FDA Pharmaceutical *Process Validation Guidance*

In Jan 2011, FDA released the *Guidance for Industry – Process Validation: General Principles and Practices* for the Pharmaceutical Industry aligning to ICH Q8/ Q9/ Q10.

Discussions with Grace McNally (FDA Officer heading the FDA committee for this Guidance document) at the Feb 21-22 ISPE Conference explained the 3-Stage approach to the Pharmaceutical Industry’s Process Validation (or “continuous verifications”) approach.

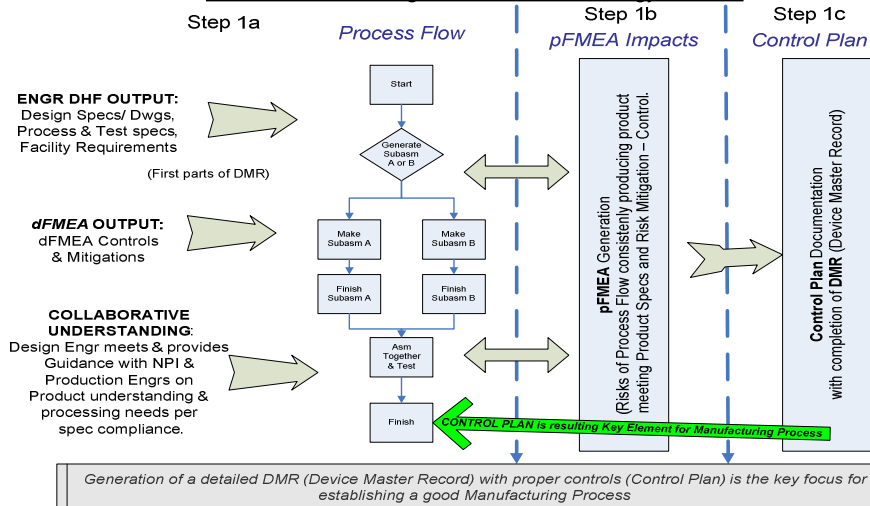
How would a Contract Manufacturer assist in pharmaceutical device-delivery per the 3-Stage approach?

Alignment to *Process Validation Guidelines... Stage 1*

Continuous Process Validation STAGE 1: PROCESS DESIGN

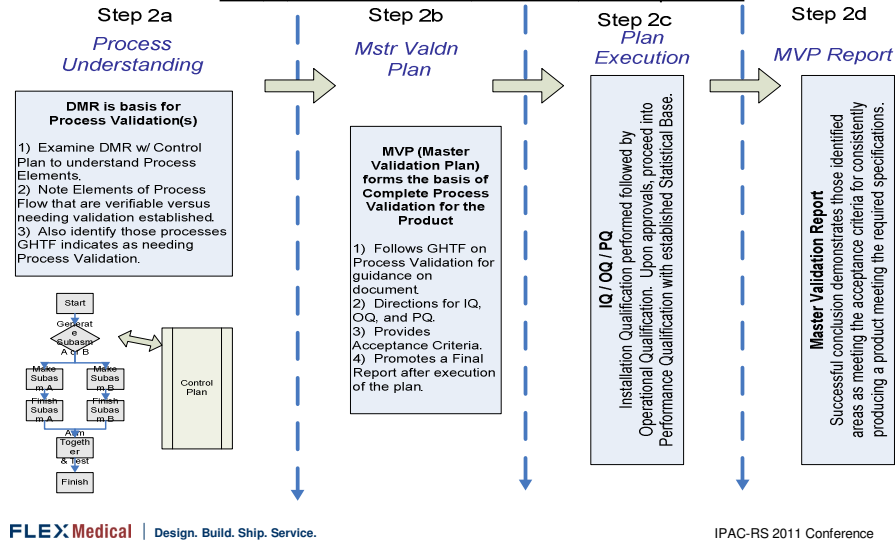
1-Building/Capturing Process Knowledge & Understanding

2-Establishing Process Control Strategy



Alignment to Process Validation Guidelines... Stage 2

Continuous Process Validation STAGE 2: PROCESS QUALIFICATION 1-Design & Qualification of Facility/Utilities/Equipment 2, 3, & 4-PPQ Protocol, Execution, and Report



Alignment to Process Validation Guidelines... Stage 3

Continuous Process Validation STAGE 3: CONTIN'S PROCESS VERIF'N 1- Continuous Process Verification

Pharmaceutical-based Goal: "Continual assurance that the process remains in a state of control (the validated state) during commercial manufacturing."

"Adhere to the CGMP requirements, specially, the collection and evaluation of information and the performance of the process, will allow for detection of undesired process variability."

FlexMedical: Utilizes the Baan and FlexQ electronic systems to identify and trace components and final assemblies throughout the ordering, receiving, fabrication/testing, packaging, and shipping environment.

"A system or systems for detecting unplanned departures from the process as designed is essential to accomplish this goal."

FlexMedical: Has established Defect Tagging of items with the defects routed to repair stations or quarantine areas for evaluation / disposition.

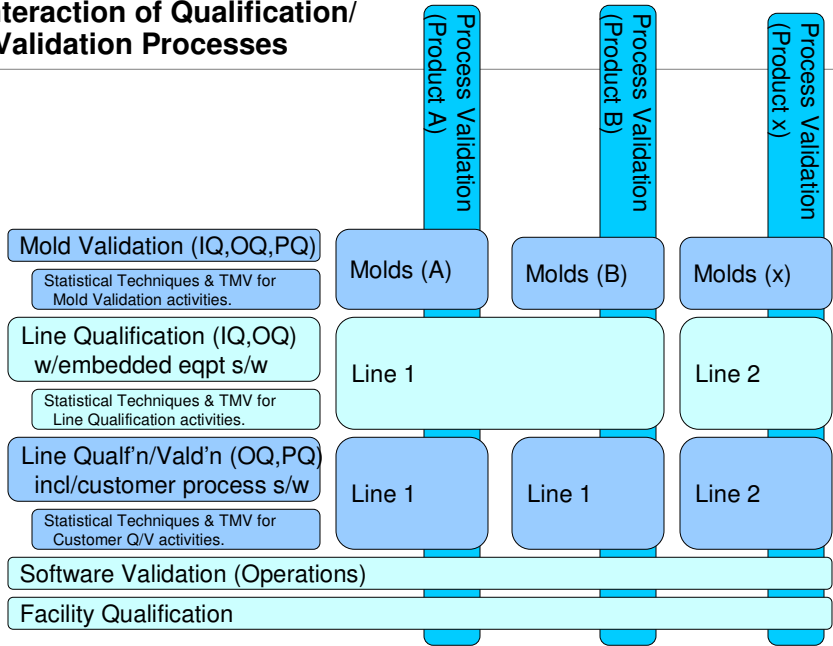
"Evaluating the performance of the process identifies problems and determines whether action must be taken to correct, anticipate, and prevent problems so that the process remains in control."

FlexMedical: Trained personnel for understanding & performing product compliance fulfillment. Also trained on CAPA activities with the FlexQ tool supporting the process.

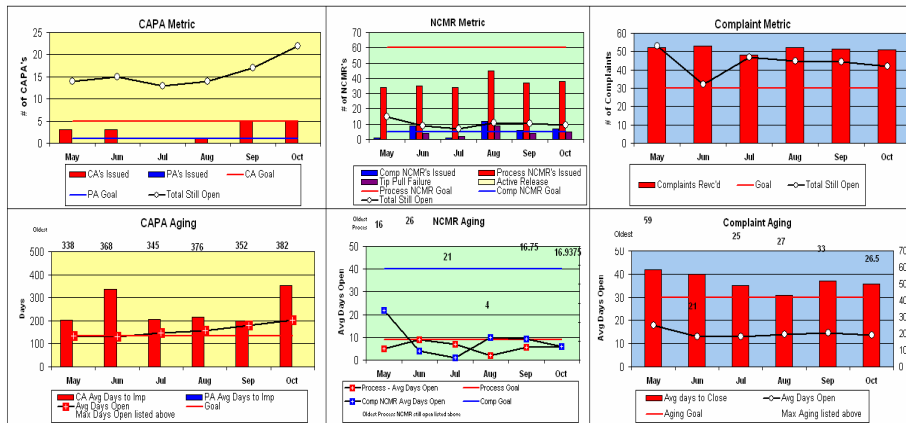
"An on-going process to collect and analyze product and process data to product quality must be established. The data collected should include relevant process trends and quality of incoming materials or components, in-process materials, and finished products. The data should be statistically trended. . . ." "Maintenance of facility, utilities, and equipment is another important aspect of ensuring that a process remains in control. "Qualification status must be maintained through . . . calibration procedures and schedules."

FlexMedical: Performs 100% of device/disposable assessed/tested to acceptance criteria during the devices/disposable fabrication process receiving and final assembly.

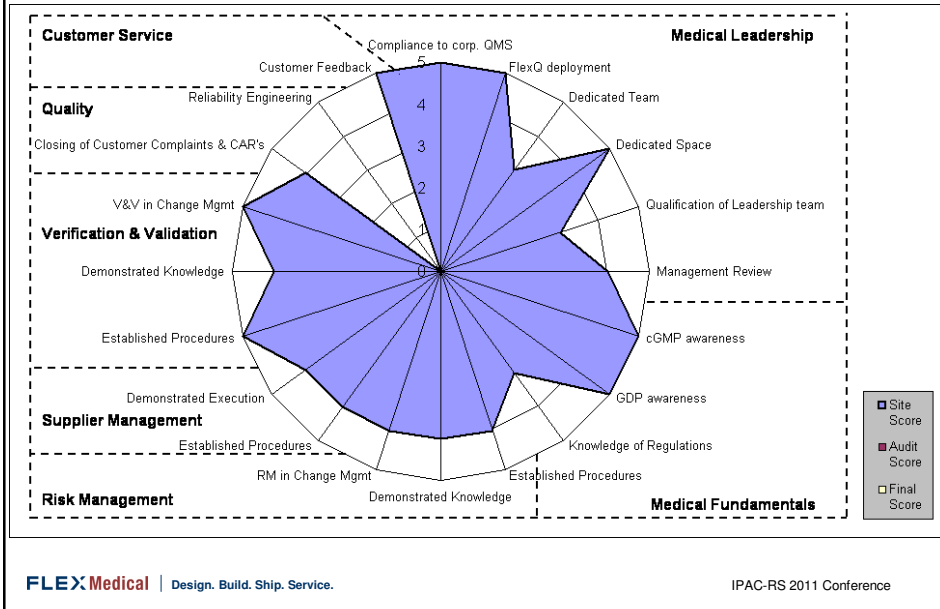
Interaction of Qualification/Validation Processes



Sample of Quality Data Reporting done every month



Sample of a Site Quality Maturity Assessment



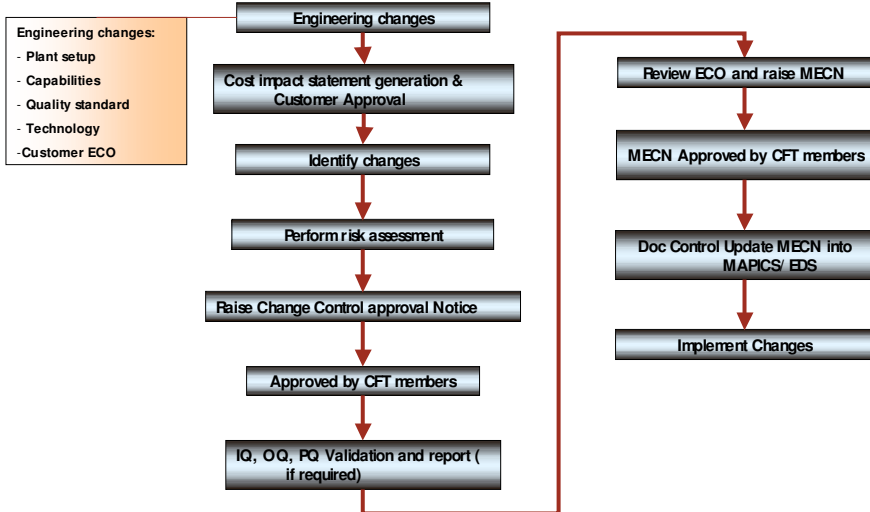
Corporate Compliance Audits, ISO & FDA Registration Status

Region	Location	Business	ISO 13485	FDA Registered	FDA Audited
AMERICAS	Aguascalientes, Mexico	Manufacturing	Yes	Yes	No
	Disposable- Asheville, NC	Plastic Molding	Yes	Yes	No
	Dallas Design - Plano	Design	Yes	No	NA
	Disposables IrvingTech Center	Design	Yes	Yes	Yes
	Juarez, Mexico	Molding	Yes	Yes	No
	Disposables San Diego, CA	Manufacturing	Yes	Yes	Yes
	Disposables Tijuana, Mexico	Manufacturing	Yes	Yes	Yes
ASIA	Beijing, China	Design	Q2FY10	No	NA
	Singapore Kallang	Manufacturing	Yes	Yes	No
	Suzhou, China	Manufacturing	Yes	No	NA
	Xixiang/GuShu, China	Manufacturing & Molding	Yes	Yes	Yes
EUROPE	Althofen, Austria	Manufacturing, Design	Yes	Yes	No
	Monza, Italy	Design	Yes	No	NA
	Timisoara, Romania	Manufacturing	Yes	No	NA

Change Management



Engineering Change Control Flowchart

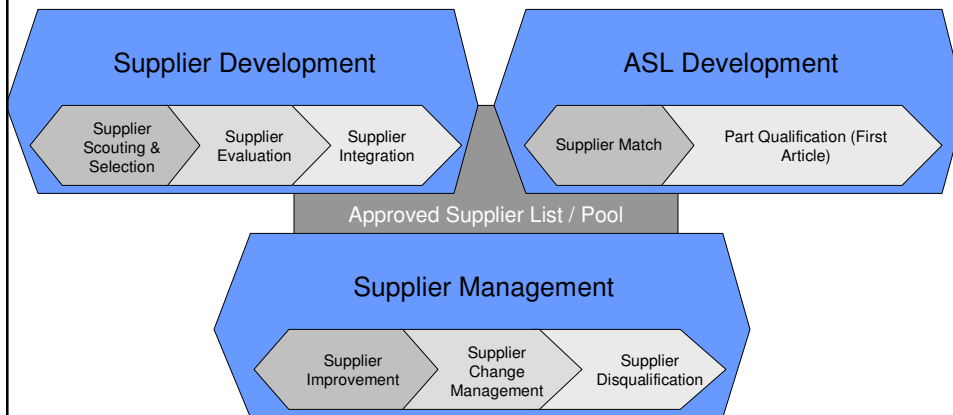


Supplier Management



Supplier Life Cycle Management (SLM)

Company's Supplier Life Cycle Process



Supplier Management

- Supplier audit

- Master supplier audit schedule
- Clear assignment between site and segment resource

- Supplier quality performance

- Collate, trend and report

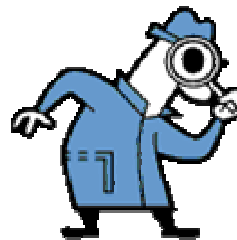
- Master Approved Supplier List

- Supplier Management

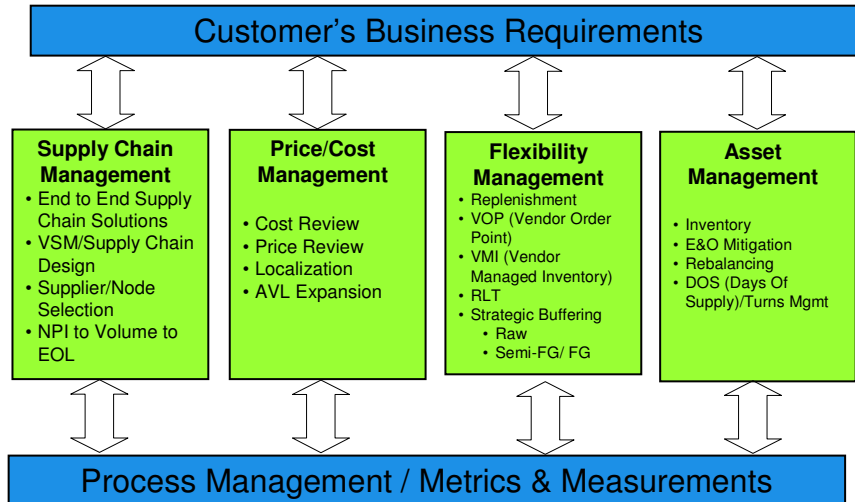
- Incoming Inspection Record Workflow
- Supplier Corrective Action Workflow
- Supplier Quality Performance Workflow

Supplier Selection

- For sources to be determined by Contract Manufacturer, suppliers are selected to assure only suitable suppliers with the right capabilities and systems are intended for the project.
- The supplier sourcing and selection are based on the requirements specific to the projects and are categorized into the following requirements i.e.
 - Capability
 - Cost
 - Financial risk
 - Quality and management system



Customer Supply Chain Management



Supplier Evaluation

- **Risk Level determination** is performed as part of the **supplier selection** and **qualification** process.
- Suppliers that are considered higher risk are identified during risk level determination exercise. Appropriate supplier audit corresponding to the risk will be conducted in order to assure the suppliers can meet the requirements shall be conducted.
- **Total risk Level** is determined by **device classification** (Medical device Class I, II, III), **component safety risk** (Custom, functional component) and **supplier risk** (single source, unique technology).
- **Type of audit**
 - Risk Level 1 – Self-assessment by supplier
 - Risk Level 2 – On-site QMS Audit at supplier
 - Risk Level 3 – On-site QMS Audit and Part Process Audit



Supplier Integration

When a supplier has been **qualified** and **approved**, the supplier will be oriented before they are placed in the **Approved Supplier List (ASL)**. Integration and orientation includes

- ✓ Order and Forecast Setup
- ✓ Quality Control and Data Submission
- ✓ Non-conformance Material Reporting
- ✓ Supplier Corrective Action process
- ✓ Product identification and traceability
- ✓ Improvement program



Approved Supplier List

- After a supplier has been **qualified**, **approved** and **integrated**, the supplier will be **uploaded into the Approved Supplier List**.
- A common platform for approved suppliers.
- Access granted to FlexMedical SQEs
- This is a FlexMedical Approved Supplier List (ASL)

Corporate Home | Finance | PMS | Global Operations | HR | IT | Legal | Marketing | ATG | VI

Welcome Kin Lee Tan

Market Segments / BU | Regional Portals

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The List: FlexMedical ASL

Home

Quality > FlexMedical ASL
FlexMedical ASL

FlexMedical Approved Supplier List

Supplier Name	Commodity	Supplier Number	Supplier Location	Country	Location City or Province	Supplier - Core Competency	Supply for Business Line	Supply for Product	Customer	Status (Approval)	Status (Preference/Customer AIC)	Supplier Risk Level	Last Audited
Alicore Precision Engineering Pte Ltd	Machining	NA	Asia - Singapore	Singapore		Good for low vol & tight tolerance machined parts	Medical Equipment	Liquid Chromatograph	Waters	Approved (Grandfathered)	Normal	2	Grandfathered on 14 Sep 2009
Arend Thermally (S) Pte Ltd	Heatbanks	NA	Asia - Singapore	Singapore		Thermal Manufacturer	Medical Equipment	Liquid Chromatograph (Waters), Gas Chromatograph (Heraeus), HPLC-ESI/MS, Electrophysiology Instrument, Amplifier (MGS-Sera), Microplate handling System (MED-Scen), PCBA (Beckhoff Automation)	Waters, Varian, Molecular Devices (GenSis), HPLC-ESI/MS, Becton Dickinson	Approved (Grandfathered)	Normal	1	Grandfathered on 14 Sep 2009
Ascent China Industries, Inc	Transformer	NA	Asia - China	Shanghai		Electrical transformer	Medical Equipment	Gas Chromatograph	Varian	Approved (Grandfathered)	Normal	1	Grandfathered on 14 Sep 2009
AGDA	Fan	NA	Asia - Other	Taiwan		A/D/C Fans & thermal	Medical Equipment	Liquid	Waters	Approved	Normal	1	Grandfathered

First Article

- Part qualification assures that all parameters (including critical requirements and processes) for the part are evaluated.
- For parts that are to be sourced, approved suppliers are matched with the parts to be supplied.
- Customer to provide critical part list that requires customer further evaluation / approval for part qualification..
- After site approval, relevant part qualification reports would be forwarded to the customer for final approval or evaluation.



Incoming Inspection Plan

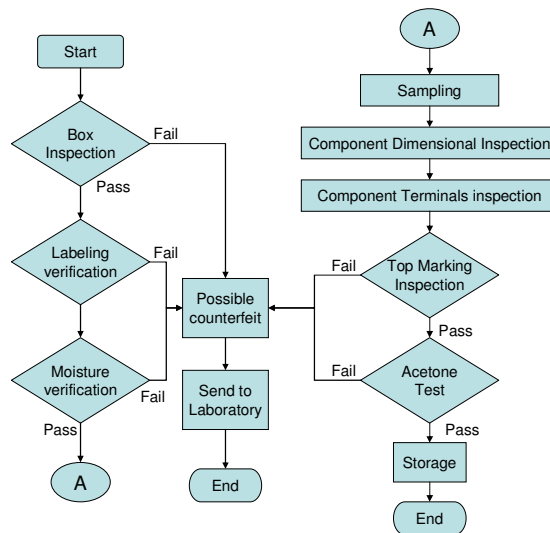
- Incoming inspection plan is developed for all parts to assure that [incoming parts are inspected according to Critical-To-Quality features](#) based on a risk level determined sampling plan.
- Customer to provide the Critical-To-Quality (CTQ) features for inspection.
- If CTQs are not defined, First Article engineer will define the CTQs.
- Incoming inspection plan contains:
 - CTQs (Attributes, Variables)
 - Inspection Method
 - Inspection Instrument (Default: discriminating 1/2 of the smallest tolerance)
 - Sampling Plan (ISO 2859; ANSI ASQ Z1.4)
 - Certificates of Compliance/Analysis Review



Counterfeit Parts

- Increasing concern due to prevailing electronics component shortage and increasing premium as a result of the shortage.
- Noted potential concerns from customers in Suzhou and in Gushu, China
- Mitigation:
 - Service Qualification Procedure MED-SQM2005
 - **Brokers are to be qualified.**
 - **Every consignment to be inspected.**
 - Flextronics Global Procurement
 - **Controlling and approving brokers worldwide.**
 - **Tighten buying process from brokers**
 - **Establish inspection for counterfeit avoidance**

Counterfeit Parts Detection



FLEXMedical

Thank You... and have a
great day!

