Plastics Injection Molding and Extrusion

Critical Manufacturing Processes for the Medical Device Industry
Dave Rittenhouse, MedAccred

- Currently Manufacturing and Supply Chain Consultant
- Retired from Plastics and Healthcare Industry
- VP Global Supply Chain Management Bayer Healthcare Diagnostics (Terrytown, NY)
- Director of Manufacturing Bayer (now Covestro) Makrolon Polycarbonate Plant (Baytown, TX)
- Plant Manager Bayer Graphic Arts Quality Films (Berlin, CT)
- Betriebsleiter (Production Superintendent) Bayer Makrolon Market Scale-Up Plant (Krefeld, Germany)
- Led Bayer European Plastics Manufacturing Implementation of then newly rolled out ISO 9001:1987 derived from BS5750
Sasha Brishkovski, Johnson & Johnson

- Supplier Quality Engineer, DePuy Synthes, Johnson and Johnson
- Lead Quality Engineer, Texas Instruments
- 20 + Years of experience
- Certified Black Belt
- Certified Senior Technology Manager (ATMAE)
- Lead Auditor ISO 13485
- Plastics
- Electronics, assembly and test
- Machining, Special Processes
Roy Holmberg, Stryker

- Advanced Sourcing Engineer, Stryker
- 10+ Years of Experience
  - 8 Years of Plastic Part Design
  - 2 Years Sourcing/Plastic Part Processing
- Licensed Professional Engineer
- ISO 13485 Certified Lead Auditor
- Experience in DFM, NPD, Special Process Validation, and FDA QSR
Agenda

- Scope
- Targeting Manufacturing Processes
- Examples of Product Issues & Challenges
- Key Process Audit Elements - Plastics
- Technical Standards Compliance
- Top Non-Conformances
- Typical Root Cause
- What is the Medical Device industry doing to improve Plastics Injection Molding and Extrusion Quality and Supply Chain Oversight?

MedAccred Plastics Injection Molding Audit
Source: MTD Micro Molding
Scope

**Medical Device Plastics Injection Molding**
- Insert Molding, Overmolding, Injection Blow Molding, Transfer Molding, Compression Molding

**Medical Device Plastics Extrusion**
- Tubing/Profile, Sheet, Film, Blown Film, Over-Jacketing, Co Extrusion Ram Extrusion

**Materials**
- Thermoplastics
- Thermosets
- Elastomers/Silicones
Targeting Manufacturing Processes

- Consistent and comprehensive practices for ensuring
  - Quality
  - Process/Product Consistency
  - Machine/Tool Reliability
  - Health, Safety, and Environment
### Examples of Product Issues & Challenges - Plastics

<table>
<thead>
<tr>
<th>Product</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusion Oxygenator w/ Arterial Filter, cardiotomy/Venous Reservoir, perfusion tubing packs</td>
<td>Identified an out-of-specification condition exhibiting <strong>additional plastic (flash)</strong> in the arterial sampling port adjacent to the arterial outlet port of the oxygenator.</td>
</tr>
<tr>
<td>Pipette tips</td>
<td>Filter Tips <strong>molded incorrectly</strong> and may not seal to the tip adaptor properly causing inaccurate aspiration and dispensing</td>
</tr>
<tr>
<td>Electric Homecare Bed</td>
<td>The failure mode is directly related to <strong>contaminated material in the plastic housing</strong> used to produce the motor. Contaminated motor housings may crack resulting in a motor that will no longer actuate the head section per the intended design. If the head section were to fall it is unlikely but possible an injury could occur. No injuries have been reported.</td>
</tr>
<tr>
<td>FMS (Fluidics Management System) Pack</td>
<td>The possible presence of a <strong>molding irregularity</strong> found within the aspiration luer which may result in a reduction of vacuum within the aspiration line.</td>
</tr>
</tbody>
</table>

Source: FDA.gov
Key Process Audit Elements - Plastics

- **End to End Manufacturing Supply Chain**
  - Material Receipt, Acceptance and Storage
  - Compounding (as required)
  - Material Preparation
  - Primary Plastics Processing
    - Injection Molding
    - Extrusion
  - Curing/Annealing (as required)
  - Secondary Processing Operations
  - Material/Product Traceability
  - Packaging, Storage and Delivery
Key Process Audit Elements - Plastics

- **Quality System Certification is Required**

- **Audit Basics:**
  - Existence
  - Comprehensiveness
  - Compliance

- **Personnel**
  - Training
  - Qualification

Source: MTD Micro Molding
Key Process Audit Elements - Plastics

**Tooling**
- Storage
- Cleaning – Process Chemicals
- Maintenance
- Assembly

Source: MTD Micro Molding
Key Process Audit Elements - Plastics

Process Validation
- Master Validation plan
- IQ, OQ, PQ
- Statistical Basis
- Measurement System Analysis
- Capability
- Process Planning Documents
- Software
- Ongoing Monitoring
- Customer Approval
Key Process Audit Elements - Plastics

**Quality Control**
- Raw Materials
- In Process – (Dimensional/Visual)
- Final Inspection

**Support Functions**
- Facilities
  - Capital Program
  - Maintenance
  - Spares Program
- Clean/White Rooms
  - Process segregation
  - Cleaning process
Technical Standards Compliance

**Cleanrooms**
- ISO 14644-1 – Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
  - Or equivalent (i.e. US FED STD 209E, BS 5295, and GMP EU)

**Medical Industry**
- QMS Certification: ISO 13485, ISO 9001, AC8004, IATF/ISO 16949
- 21 CFR Part 820
Top Non-conformances

- Comprehensive documentation of processes – various gaps within existing procedures
- Clean room/white room procedures
- Software controlled equipment procedures
- Master Validation Plan
Typical Root Cause

- “Tribal Knowledge”
- Misunderstanding the requirement or unaware of requirement
- Lack of procedure, procedure was not well defined, or not in-depth
What is the Medical Device industry doing to improve Plastics Injection Molding & Extrusion Quality and Supply Chain Oversight?

MedAccred Plastics Task Group
- Baxter; Becton, Dickinson & Co.; Johnson & Johnson; Philips; Stryker
- Open to Subject Matter Experts from OEMs, CMs and Suppliers
- Develop Audit Criteria
- Approve SME auditors
- Grant Supplier accreditations

OEMs/CMs use MedAccred Accreditation a criteria to award new business and oversee their critical process supply chain quality

Suppliers use MedAccred Accreditation to ensure final product quality and improved manufacturing operations
Questions?

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