WHAT THE FDA REQUIRES OF MEDICAL DEVICE MOLDERS

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About – Bob Mehta

- Principal Consultant & Recruiter – Over 25 years of experience including 6+ years as a Principal Consultant/Recruiter at GMP ISO Expert Services.
- Help Device, Pharma, Combination Products, Food/Dietary Supplement, Cosmetic, and Aerospace clients with gap analysis, implementation/remediation of Quality Systems as a result of FDA warning letters, Consent Decree, ISO/AS9100/ICH Audits and continuous improvement initiatives using lean / six sigma methodologies.
- Industry Board of Advisor – Medical Device Industry Education Consortium.
- Author of Articles – Published in Pharmaceutical Technology, MD&DI, Nutraceutical World, and Quality Progress publications.
- Adjunct Professor at Cal State Dominguez Hills teaching courses for the Masters of Science in Quality Assurance program, at Cal Poly Pomona teaching Six Sigma Blackbelt course, and provides training on American Society for Quality (ASQ) certification courses
- Nominated as a Fellow by ASQ Nov 2014
- Provided consulting service to injection device molders; Reny & Co., Accellent, C. Brewer, and Helix Medical

What the FDA Requires of Device Molders

- Plastic Medical Device Molder Growth Reasons
- Food & Drug Administration (FDA)
- FDA requirements for Device Molders
- Warning Letter Example
- Learning from experience

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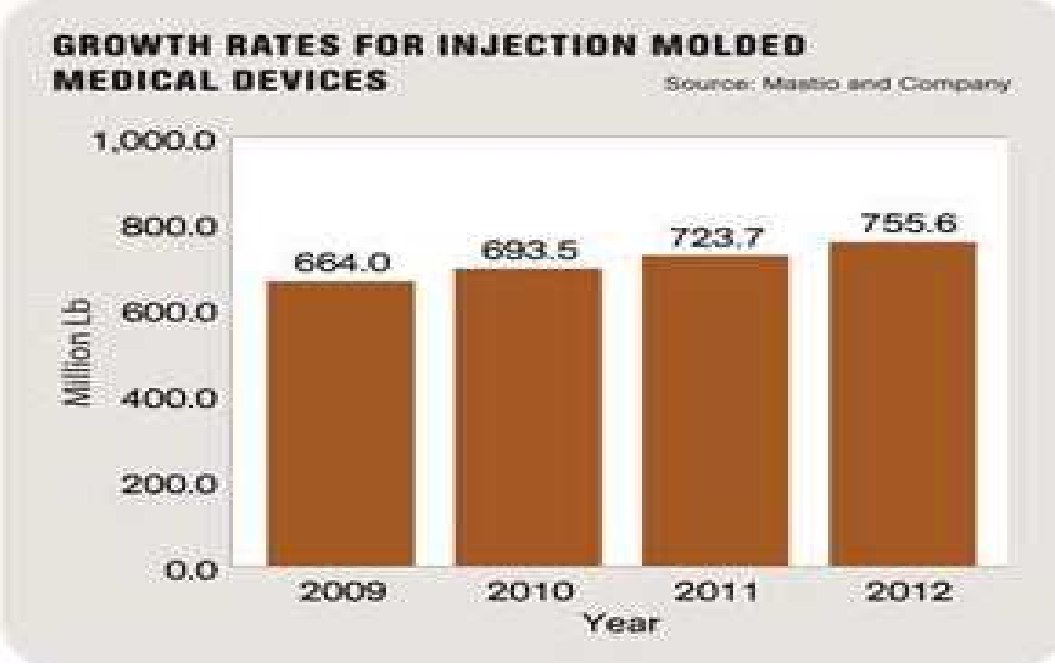
What the FDA Requires of Device Molders

- Plastic Medical Device Molders Growth

  Corresponding to revenues in excess of $1Billion in 2012 and expected to grow $1.5 billions by 2018
  Source: http://www.plastics.com/medical/molding-HTI-Plastics.html



What the FDA Requires of Device Molders

Reasons for Growth

- Relatively few metals suitable for use in the human body
- Cost effective (vs. metal)
- The graying of the world's population
  - The total number of people aged over 65 expected to rise to 800 million by 2025, expected increase of up to 300%of the older population
  - Need for use of single-use device and cost effective to use plastic

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- Medical device molders must register to the FDA before starting selling products to medical device clients.

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What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- The **Code of Federal Regulations** (**CFR**) is a codification of the general and permanent rules published in the **Federal** Register by the Executive departments and agencies of the **Federal** Government.
- **Title 21** of the **CFR** is reserved for rules of the Food and Drug Administration
- 21 CFR 820 regulations for medical device

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart A--General Provisions**
      - § 820.1 - Scope.
      - § 820.3 - Definitions.
      - § 820.5 - Quality system.
    - **Subpart B--Quality System Requirements**
      - § 820.20 - Management responsibility.
      - § 820.22 - Quality audit.
      - § 820.25 - Personnel.

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart C--Design Controls**
      § 820.30 - Design controls. (device manufacturer is responsible)
    - **Subpart D--Document Controls**
      § 820.40 - Document controls.
    - **Subpart E--Purchasing Controls**
      § 820.50 - Purchasing controls.
    - **Subpart F--Identification and Traceability**
      § 820.60 - Identification.
      § 820.65 - Traceability.

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart G--Production and Process Controls**
      § 820.70 - Production and process controls.
      § 820.72 - Inspection, measuring, and test equipment.
      § 820.75 - Process validation.
    - **Subpart H--Acceptance Activities**
      § 820.80 - Receiving, in-process, and finished device acceptance.
      § 820.86 - Acceptance status.

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart I--Nonconforming Product**
      § 820.90 - Nonconforming product.
    - **Subpart J--Corrective and Preventive Action**
      § 820.100 - Corrective and preventive action.
    - **Subpart K--Labeling and Packaging Control**
      § 820.120 - Device labeling. (device manufacturer is responsible)
      § 820.130 - Device packaging. (device manufacturer is responsible)

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart L--Handling, Storage, Distribution, and Installation**
      - § 820.140 - Handling.
      - § 820.150 - Storage.
      - § 820.160 - Distribution.
      - § 820.170 - Installation.

What the FDA Requires of Device Molders

Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart M--Records**
      - § 820.180 - General requirements.
      - § 820.181 - Device master record.
      - § 820.184 - Device history record.
      - § 820.186 - Quality system record.
      - § 820.198 - Complaint files.
    - **Subpart N--Servicing**
      - § 820.200 - Servicing. (for large equipment manufacturer)
    - **Subpart O--Statistical Techniques**
      - § 820.250 - Statistical techniques.

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Food and Drug Administration (FDA)

- 21 CFR Part 820 – Quality System Regulations
  - **Subparts**
    - **Subpart M--Records**
      - § 820.180 - General requirements.
      - § 820.181 - Device master record.
      - § 820.184 - Device history record.
      - § 820.186 - Quality system record.
      - § 820.198 - Complaint files.
    - **Subpart N--Servicing**
      - § 820.200 - Servicing. (for large equipment manufacturer)
    - **Subpart O--Statistical Techniques**
      - § 820.250 - Statistical techniques.

What the FDA Requires of Device Molders

Cleanroom

- A clean room is a location that maintains a controlled level of environmental pollutants - also known as contamination. These pollutants may include dust, chemical vapors, aerosol particles or airborne microbes.
- Clean room areas require a steadily maintained level of control of these pollutants which lead to part contamination. These particles are measured as per the amount found within a specified area - which is measured by the cubic meter of air.
  - A certified ISO 7 clean room is 10,000 particles of pollutants per cubic foot
  - An ISO 8 certified clean room is 100,000 particles of pollutants per cubic foot

What the FDA Requires of Device Molders

FDA Warning Letter to device molders

FRANTZ TOOL & DESIGN

Plastics: Engineering & Injection Molding

June 5,2009

Ref: **2009·DAL-WL·12**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Joe Lee Frantz
Vice President and Co-Owner
Frantz Design, Inc.
3202 Oakmont Blvd.
Austin, Texas 78703-1346

What the FDA Requires of Device Molders

FDA Warning Letter to device molders Frantz Tool & Design

- Failure to establish and maintain a device design history file for each type of device to include or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the design control requirements of 21 C.F.R. § 820. as required by 21 C.F.R. § 820.30U). See FDA 483 Item 3.
  - Specifically, other than some product brochures that list the length and firmness specifications of the elastic straps, your firm has not maintained a design history file to document the design changes made to the EMA devices and their injection molding process as described above.

What the FDA Requires of Device Molders

FDA Warning Letter to device molders Frantz Tool & Design

- Failure to validate with a high degree of assurance a manufacturing process whose results cannot be fully verified by subsequent inspection or test, approve the validation according to established procedures, and document validation results and activities, as required by 21 C.F.R. § 820,75(a); and failure to revalidate a manufacturing process when changes or process deviations occur, as required by 21 C.F.R. § 820.75(c). See FDA 483 Items 4 and 14.
  - Specifically, neither your firm nor your contract manufacturer has validated the injection molding process used to manufacture the devices' elastic straps in order to detect problems and ensure that this product consistently meets its quality specifications. For instance, the use of the **(b)(4)** material during the injection molding process caused the blue elastic straps to break during patient's use in March 2008. Further, your firm has not revalidated the injection molding process when your firm changed the **(b)(4)** to increase the strength of the elastic straps in response to complaints of broken elastic straps.

What the FDA Requires of Device Molders

Learning from Experience

- The Quality control systems for FDA Registered and ISO 13485:2003 certification standards include raw material and lot number controls, process parameter controls, record keeping and environmental controls.
- Most of the molders are either certified to ISO 9001 or ISO 13485 certification which are standards vs. FDA's 21 CFR 820 is regulations
- One must comply to regulations…..why
  - FDA is the most powerful entity and can shut down business by giving consent decree to the manufacturer who has significant gaps against requirements and/or repeated violations.

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What the FDA Requires of Device Molders

How one can start?

- Hire a seasoned consultant with a proven track record to establish quality system compliant to ISO 13485 and then 21 CFR Part 820 to meet customer requirements
- Provide training to employees on all documents before they perform tasks
- Hire competent workforce with experience with the FDA's Quality System Regulations
- Management support to invest in people and technology to consistently manufacture products with superior quality

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Implementing Effective CAPA Process

Thank you for your participation

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