

ASQ Worcester Section

**Successful Inspections:
ISO 13485 and FDA**

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Successful Inspections: ISO 13485 and FDA

Inspections - Similarities
Inspections - Differences
**New: Subcontracting / Contract
Manufacturing**
Key Success Factors

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Successful Inspections: ISO 13485 and FDA

How good is our Quality System ?
**[How good is ...our Quality Department?
... Our Quality Manager?]**
Will we pass "The Inspection / Audit" ???

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Inspections

Certification/Notified Body (NB): **Certification**
Evaluate if the company is managing and operating in compliance with the requirements for certification to ISO 13485.

Food and Drug Administration (FDA): **Enforcement**
Evaluate if the company is managing and operating in compliance with the applicable laws and regulations, including 21 CFR 820, and to collect evidence of noncompliances.

Inspections – Similarities

**To many, both appear to be the same
Necessities to the Business
Both Quality Systems have many common
elements and requirements**
ISO 13485:2003 Medical Devices – Quality
management systems – Requirements for
regulatory purposes
21 CFR, Medical devices, Part 820, Quality
System Regulation, Current good
manufacturing practice (CGMP)

Inspections – Differences

NB: **A Certification Activity**
Inspections start with an agreed upon date

FDA): **An Enforcement Activity**
Inspections start with an FDA 482

Inspections – Differences

The basic relationship

NB: \$\$\$ Hired by the company

FDA: No Choice

Inspections – Differences

The possible outcomes

NB: Nonconformances to fix
Major – Minor - Recommendation
Certification
Next audit – 1 year
Confidential

Worst case:
Hold up (withdraw?) Certification

Inspections – Differences

The possible outcomes

FDA: Nonconformances to fix/Turbo EIR
NAI – VAI - OAI
Next audit – ?? years away
Public disclosure (FOI and www)

Worst case:
Letter / Warning Letter
Administrative Sanctions
Seizure / Injunction / Consent Decree
Civil / Criminal Penalty: \$\$\$/Jail

Inspections – Differences

Executive Management

NB: Business impact
Respect

FDA: Liability impact
Business impact
Respect

Inspections – Differences

The Inspection Process

Agreed upon vs. “surprise”
Frequency
Inspection plan/Checklist vs. QSIT
Duration
Full and Surveillance/Abbreviated
Formality / Legalism
ISO 13485 vs. 21 CFR 820
Limitation to certain documents/records

FDA's QSIT: Quality System Inspection Technique

Management Controls

Design Controls

CAPA

Production and Process Controls

http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

Inspections – Differences

The Inspection Process

- Formality / Legalism
- Policy for FDA
 - FDA's credentials and FDA 482
 - Minutes
 - Copies (2) – Confidential
 - Affidavits
 - Cameras
 - Limitation to certain documents/records

NEW: Subcontracting and Contract Manufacturing

- GHTF Guidance (requirements)
- Pushed by the “buyer” company
- Pushed by the NBS and by FDA
- Who is the responsible “manufacturer”

Key Success Factors

- The most important success factor:
 - A Sound Quality System !

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Key Success Factors

A Sound Quality System

Implementation

Operational Compliance

Improvement

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Key Success Factors

A Sound Quality System

Internal Audit System:

Quality System,

AND

Regulatory requirements

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Key Success Factors

The most important success factor:

A Sound Quality System !

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Key Success Factors

The **second most important success factor:**

Being FULLY prepared to manage an inspection*.

* It can be blown!

Key Success Factors

**Conduct a "FIRE*" drill,
and a
Mock NB/FDA Inspection**

* *FIRE = Full Inspection REadiness*

Key Success Factors

- A. Company Policy for Inspections**
- B. Company Inspection Procedure**
- C. Review (with NB/FDA eyes) what they have now.**
- D. Review (with NB/FDA eyes) what they will ask for first.**
- E. Prepare a NB/FDA Inspection Plan/Strategy**
- F. Conduct a "FIRE" drill (do all of the above)**
- G. Conduct a Mock audit**

Key Success Factors

- Company FDA Inspection Policy**
- FDA's credentials and FDA 482 Minutes**
- Copies (2) – Confidential Affidavits**
- Cameras**
- Limitation to certain documents/records**

Key Success Factors

- Company Inspection Procedure:**
- Roles and Responsibilities**
- Receptionist**
- Executive Management**
- Rest of Company**

Key Success Factors

- Company Inspection Procedure (cont):**
- Communications Plan**
- Executive Management**
- Inspection Team**
- Rest of Company**
- Training – Training - Training**

Key Success Factors

Company Inspection Procedure (cont):

- Audit Room contents
- Computer Access
- Housekeeping: cleanups / walk abouts
- Refresher training: especially Do's and Don'ts
- Manufacturing schedule/activity review

Key Success Factors

- Review (with NB/FDA eyes) what they have now
 - Registrations, Listings, Quality System Changes
- Past Inspection records:
 - Nonconformances and reports
 - A record that everything has been addressed
- The company's files
- Company Web site
- NB/FDA web site

Key Success Factors

- Review (with NB/FDA eyes) what they will ask for first
 - Product: Catalog or List
 - Quality Manual
 - Top SOPs: Management Responsibility, CAPA, Complaints, Internal Audit Vigilance-MDR, Design Control
 - Organization Chart
 - Facility diagram, floor plan, or layout

Key Success Factors

- Prepare an Inspection Plan/Strategy**
- Strengths – how to bring them out**
- Weaknesses – how to deal with them**
- Obvious targets – ex: Sterility, Final Test, etc.**
- Overview, expectations, and first impressions**
- Language / translations & QMS uniqueness**
- Communications and Certifications drafted**
- Changes since the last inspection**
- Have final preparation checklists ready**
- Keep the Plan/Strategy current**

Key Success Factors

- Take care of your Top/Executive Management**
- Inspection Readiness / reassurance**
- Training**
- Job Description**
- Questions and Answers**
- Expectations, and first impressions**
- Do-s and Don't-s**

Key Success Factors

- Conduct a "FIRE" Drill**
- Conduct a Mock Audit**

Key Success Factors

Company Wide Training – an outline

- Overview
- Review company's Inspection Policies
- Review company's Inspection Procedure
- Review what to expect
- Review common NB/FDA questions/answers
- Review inspection DOs and DON'Ts

Key Success Factors

During the Inspection

- Arrival and opening meeting:
 - The NB/FDA follows their procedures
 - Company follows their procedures
 - The Company = Senior Management and The Inspection Team
- Be guided by your planning and training
- Be Flexible

Key Success Factors

During the Inspection

- Remember, the NB/FDA:
 - run the show
 - ask the questions
- “Show me” :
 - records, data, documents, studies, reports ...

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Key Success Factors

During the Inspection

- Confirm issues/483's as you go along
- Clarify - Clarify - Clarify
- Be very careful about fixing or even promising to fix issues
- Do not argue ... with NB/FDA or each other
- Daily: End of day Summaries

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After the Inspection

No Nonconformances/483s ? ? ?

Well Done !!!

- Your Quality System
- Your Inspection Management

Congratulations !

CELEBRATE !!!

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Key Success Factors

After the Inspection

The 4 Action Item Lists

- The NB/FDA's List of nonconformances/483s
- The NB/FDA's "recommendations"
- The NB/FDA's Report/EIR
- Your own Lists of observations/findings

Address and Document the closure to ALL of these. What was or was not done must be clear for the next Inspection Team

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Key Success Factors

After the Inspection

Communication

**Remember to publish a summary
Internally, and
Externally, if appropriate**

Key Success Factors

After the Inspection

Responding to the Nonconformances/483s

**FDA: It is voluntary, but do it!
NB: case by case
Respond within 2 weeks.
An additional narrative letter/report may be
appropriate.**

Key Success Factors

Responding to FDA 483s

**Interpret very carefully each 483; then plan how
best to respond, item by item, to the FDA.
Fix what you can; provide root cause, correction,
corrective/preventative action and evidence
of the implementation.
Provide a plan for the rest. Give dates that will
not be missed. A completed root cause
analysis is helpful. Provide regular progress
reports. Over-communicating to FDA is OK.
Get expert help if the company does not have
this experience/expertise in house.**

Final Notes

- It will be hard**
- At times it will be stressful**
- Things will go wrong**
 - Someone may say too much, or the wrong thing
 - The inspector may find 'that' document
 - It may take longer than desired to find a document
- Keep it professional**
- When they leave; It's not over**

Preparation ensures success!

The caribou feeds the wolf, but it is the wolf who keeps the caribou strong.

Keewatin Inuit proverb

Thank You !

?? What is the World's Largest Tree ??

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