Regulatory Impact on Medical Device Quality Management Systems

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Presentation Slides

• This slide deck is the presentation performed on 2015-09-10.
  
  • A more detailed slide deck will be posted with expanded information in a number of the slides, and additional references and resources added within the next few weeks.
  
  • Please check back on the ASQ Baltimore website for the expanded version

  • Alternatively, email efinegan@asqbaltimore.org to get a notice when the slide deck is posted.
Regulatory Environment

- Complicated network of regulations, laws, standards, guidances that impact the manufacture and sale of medical devices
- International regulatory changes have a significant impact on the ability for a company to get its product to market
Why should Quality care?

• Quality and Regulatory have been linked with product, service and process development for some time

  • ISO 13485:1996 – Medical Device Quality system.
  • ISO 14000 (BS 7750:1992) – Environmental
  • ISO 22000 – Food safety management
Why should Quality care?

- Within the Medical Device regulatory world, regulatory requirements have been an input into product design, but also the quality management system
  - FDA regulations 21 CFR 820, “GMP”.
  - For years, the FDA GMP requirements were the “standard” around the world.
  - ISO 13485:1996 changed this, attempting global harmonization which fell a little short
Why should Quality care?

• Because Regulatory is moving in to our turf . . .

• Because Regulatory is making our jobs harder. . .

• Because Regulatory decision-makers know that implementing a correct Quality system framework is the best way to put safe and effective medical devices out in the market . . .

• Because Regulatory decision-makers realize that a globally harmonized quality system is the best way to meet that goal . . .
QMS Impacts

- Supply chain
- Audit burden
- MDSAP program
- QMS Certification Choices
- Post-market surveillance
- Qualified person
- General business impacts (resources, costs, etc)
Supply Chain Impact

- Although currently driven by Europe, major regulatory bodies are now scrutinizing the supply chain much more than before
  - Poly Implant Prothéses Scandal
- Contract Management
  - ISO 9001:1994 had “Contract review”, and future versions of the standard moved that under customer requirements.
Supply Chain Impact

• Unannounced Audits
  • Europe is directly looking into suppliers
  • FDA and Health Canada are looking into indirect enforcement

• New standards / regulations
  • ISO 13485:201x is now expanding its scope to suppliers of medical device manufacturers.
Supply Chain Impact

• Risk-based
  • The entire review of supplier management will need to be risk-based.
  • Move within quality community to review/document decisions across all aspects of the QMS
    – “risk-based” thinking / “risk-based” approach
    – documentation increase of risk based decisions
Supply Chain Impact

- Practical Implications
  - Supplier management is expected to increase
  - “Approved supplier list” will not be adequate
  - Risk based management of crucial suppliers / critical suppliers and suppliers of critical components will be required
  - Documentation of supplier reviews will become necessary, particularly for Notified Bodies
  - Balance of what suppliers are determined to be critical versus non-critical
Audit Burden

• Regulatory requirements impact manufacturers
  
  • Announced audits.
    – Scheduled and under control of the manufacturer
    – For example, internal audits, registration/surveillance audits and supplier audits
  
  • Unannounced audits.
    – Variety of unannounced audits are now required to be performed for medical device manufacturers
Announced Audits

• Internal audits
  • Already exist within current QMS framework
  • New requirements (regulatory, technical file, MDD)

• Registration/Surveillance audits
  • ISO 9001 / ISO 13485 audits.
    – will include be impacted by MDD, CMDCAS/MDSAP
Announced Audits

- **Organization-Supplier audits**
  - Already exist within current QMS framework
  - Your suppliers will be impacted by new requirements

- **Customer-Supplier audits**
  - Already exist within current QMS framework
  - Customers will be impacted by new requirements and your organization may be audited based on risk/requirements
Unannounced Audits

• Types of Unannounced Audits:
  • FDA Inspections
  • EU Notified Body Audits
  • MDSAP Audits
  • EU Importer/Distributor Audits (proposed)
  • NTRL Product Audits
Unannounced Audits

- FDA Inspections
  - FDA inspects medical device manufacturers.
    - No statutory authority to audit suppliers, only if they already produce medical devices
  - Currently, 5 day notice.
  - MDSAP program – impact.
Unannounced Audits

• EU Notified Body Audits
  • New style of “unannounced” audits
    – Unannounced, “10-minute rule”
    – Minimum once every three years, risk-based
    – Multiple auditors, cost borne by manufacturer
  • Reasons why
    – European Growth, no updates in 20 years
    – Poly Implant Prothéses Scandal
Unannounced Audits

• EU Notified Body Audits
  • Notified Bodies audit technical files for products placed on markets
  • Notified bodies will audit manufacturers and suppliers
    – At least 2 audit-days (depending on the device)
    – Two auditors will be used per unannounced audit, instead of a single auditor
  • Notified bodies reserve the right to audit through the supply chain (risk based)
Unannounced Audits

• EU Notified Body Audits
  • Manufacturers - Practical Impact
    – Unannounced audits will need to be accepted, rejection will mean loss of ISO 13485
    – Constant information on production schedules to Notified Bodies is required, depending on your business
    – Production line will need to be “running” to provide access to auditors without notice
    – Audits will include technical file and physical review
Unannounced Audits

- EU Notified Body Audits
  - Manufacturers - Practical Impact
    - Personnel will need to be available without notice to accompany auditors
    - Internal auditors will need to add EU-focused audits to ensure that any unannounced audits will be successful
    - Post-market surveillance and Vigilance records will be more important in the future, and may be copied during the audits to be added to the regional databases
Unannounced Audits

• EU Notified Body Audits
  • Suppliers - Practical Impact
    – Audits will be unannounced for suppliers
    – Suppliers will be audited against their quality management systems, even if they do not have one.
    – If suppliers do not allow the audit to proceed, immediate suspension of ISO 13485 certificates
    – Expectation that contractual requirements will be in place
Unannounced Audits

• EU Notified Body Audits
  • Suppliers - Practical Impact
    – Suppliers will need to be actively managed, rather than passively
    – Contracts with suppliers will need to make them aware that they may be audited.
    – Contracts with supplier good idea to give them a “heads up” about what is upcoming.
Unannounced Audits

- EU Notified Body Audits
  - Suppliers - Practical Impact
    - Notified Bodies will consider contract management with suppliers part of supplier management (i.e., no contracts implies that Notified Bodies cannot audit suppliers, a violation of MDD requirements)
    - Current proposal requires companies to include supplier’s suppliers.
Unannounced Audits

• EU Notified Body Audits
  • Suppliers - Practical Impact
    – Companies need to be clear on definition of critical suppliers and how they are designated and reported to the Notified Bodies
    – Any changes to the status of critical / non-critical supplier will need to be justified to the Notified Bodies
    – If suppliers reject audits and ISO 13485 certificate is rejected, it is unknown this will impact MDSAP
    – Manufacturer will not be notified that the audit is occurring. Supplier will probably inform.
Unannounced Audits

• EU Notified Body Audits

  • Suppliers - Practical Impact
    – Relationships with our individual suppliers will become more important
    – Ease of simply changing suppliers needs to be managed with the regulatory impact to be taken into account
    – Business risk – an unhappy supplier can jeopardize our ISO 13485 certification.
Unannounced Audits

- NTRL Audits
  - Safety and EMC testing – product audits.

- EU Importer / Distributor audits
  - EU is changing the current Medical Device Directive (MDD)
  - Importers will be held responsible for product received from manufacturers
  - Distributors will be responsible for compliance of products received from importers/distributors
  - Expected to take effect in 2017
MDSAP – What is it?

- MDSAP = Medical Device Single Audit Program
  - MDSAP is intended to allow recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities
  - Based on ISO 13485:2003
  - Pilot program begun January 2014, ongoing
MDSAP – Countries involved

• Initially 4 countries are signatories to the Pilot program
  • Australia
  • Brazil
  • Canada
  • United States

• Additionally, other countries/agencies are observers
  • Japan
  • Europe, China, Russia
  • World Health Organization (WHO)
MDSAP – Countries involved

• Practical Impact – Regulatory standpoint
  • For any item being audited, the most stringent countries’ requirements will apply
  • Results from any audit will be sent to any MDSAP country where manufacturer has products
  • Idea of a single audit covering every country will be a benefit (fewer audits, cost savings).
MDSAP – Audits

- Practical Impact – Auditing standpoint
  - Limited number of auditing organizations
  - Limited number of auditors
  - Auditor requirements are very stringent
  - Problem with all MDSAP Auditing Agencies moving forward
  - Estimations by regulators are that audits will be 35% to 100% longer than CMDCAS audits
MDSAP – Audits

• Practical Impact – Auditing standpoint

• Audits will be QSIT-style (process based) audits, falling under the CAPA+1 for surveillance and the entire system during registration, with particular focus on:
  – Management
  – Measurement/Analysis/Improvement
  – Design and Development
  – Production and Service Controls
  – Purchasing / Supplier Management
  – Authorizations / Registration / Adverse Event / Advisory Reports
MDSAP – Audits

• Practical Impact – Auditing standpoint
  • All audits shall be expected to be much more in-depth than current ISO 9001 / ISO 13485 audits
  • Non-conformities will be graded in 5 levels. Most serious non-conformities will be closed out via an unannounced MDSAP audit
  • All regulatory bodies will receive audit results, good or bad. One bad audit will flag all relevant regulatory bodies.
  • Management Reviews, internal audit results and supplier audit results will be eligible to be provided to the FDA (not currently)
MDSAP – Audits

• Practical Impact – Auditing standpoint
  • MDSAP materials provide useful training materials for organizations (even non-medical)
MDSAP – FDA View

• FDA is performing both QSIT and MDSAP audits
  • Unknown when FDA will switch completely from QSIT to MDSAP
  • May require Congressional involvement.

• FDA is allowing MDSAP audits to substitute for “routine audits”
  • Does not benefit smaller companies who may not being routinely audited
  • Additionally, benefit lasts for a year and MDSAP audits are required to be performed annually
MDSAP – Canadian View

• Canada is currently performing the CMDCAS program
  • CMDCAS is ISO 13485 with a number of specific requirements introduced by Health Canada
  • Limited number of auditing companies to perform CMDCAS audits
MDSAP – Canadian View

• CMDCAS ➔ MDSAP
  
  • Although a pilot program, MDSAP will be replacing CMDCAS in January 2017
  
  • This forces the switch from a voluntary program to a mandatory program for any country selling into Canada and the U.S.
  
  • Fewer auditors will be available for the MDSAP program
QMS Certifications

- ISO 9001 and ISO 13485
  - Although once well harmonized, they have been drifting apart.
  - ISO 13485 has not followed the new ISO High level format.
  - If the company wishes to maintain both ISO 9001 and ISO 13485 standards, there will be more work involved moving forward.
Post market surveillance/vigilance

- Regulatory requirements worldwide for post-market vigilance, surveillance, adverse event review, product service issues are increasing
  - Increases to existing complaint / non-conformance management program.
  - Management review of results are becoming expected (regulation / ISO 13485).
  - Risk management moving from a regulatory / design expectation to a general quality aspect of the product.
Qualified Person (EU)

• Definition

  • “manufacturers must have available within their organization at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.”

  • Expertise shown via:

    – A diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;

    – Three years of professional experience in regulatory affairs or in quality management systems relating to medical devices.
Qualified Person (EU)

• Resource impact
  • Although a “regulatory” requirement, for companies who outsource regulatory requirements, quality personnel may be called on to perform QP duties.
  • May already exist within the projects.

• Responsibilities
  • Conformity of the devices is appropriately assessed.
  • Review of corrective actions, vigilance, incidents
  • Necessary filings to regulatory bodies
Practical Impacts

• Increased Costs for Manufacturers

  • Financial.
    – Work required to meet new requirements
    – Cost of new certifications
    – Flow-down costs (goods from suppliers)
    – (MDSAP) Audit costs will increase, shift to manufacturer

  • Resources.
    – Audits will increasingly rely on SME/Regulatory personnel to meet needs
Practical Impacts

• Stricter requirements impacting the regulators
  • Notified Bodies, shortage of auditors.
  • Longer times for audits mean impact on schedules
  • Notified Bodies are leaving the medical device field due to increased requirements
  • Manufacturers will need to manage certification program
  • “Special” Notified Bodies will be created for higher-risk devices, stretching resources
Practical Impacts

- Increased costs of medical devices
  - Financial.
  - Supply impact.

- Audit exposure
  - Audits for certification are normally used not only for market requirements, but for improvement
  - Audit result exposure can have a larger impact on manufacturers (good or bad)
Practical Impacts

- Difficulty in gaining entrance into markets
  - Greater time-to-market, upfront resources.
  - Greater “paperwork” burden.
Practical Impacts

- Peripheral impacts of upcoming regulatory issues
  - Cyber-security
  - Protected Health Information
  - Unique Device Identifiers
  - Additive Manufacturing (3D printing)
  - Mobile health devices
  - Medical device follow-on from Pharmaceutical
Questions?

Thank you