CardinalHealth
Essential to care™

Logistics
Product
Business
Patient

MDSAP

Medical Device Single Audit Program

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

CardinalHealth
Essential to care™

CardinalHealth
Essential to care™
Logistics
Product
Business
Patient

MDSAP Overview

- Benefits
- Challenges
- Lessons learned.

CardinalHealth
Essential to care™
Logistics
Product
Business
Patient

MDSAP- Positives





- One audit for all regulators involved
- Thorough audit of QMS.
- Predictability of audit-MDSAP checklist and MDSAP companion document can be used to prepare for audit.
- Qualitative grading system (1-5)- removes subjectivity. Based on direct/ indirect impact to device safety and performance.

CardinalHealth
Essential to care™

Logistics
Product
Business
Patient

MDSAP- Challenges

- Faster paced audit, stayed on track to schedule- each chapter of companion document must be completed within allocated time.
- Depending on the audit result - Unannounced audit within 6 months, by potentially all regulators.
- More audit days- # of activities & region(s) product sold into (not # of personnel).
- Multiple audit streams (+ AO trainees) & site tours.
- Extensive documentation requests- > 300 day.

Lessons learned

- Speed of execution essential- objective evidence readily available to meet allocated times.
- Pre- stage SME's- ready!
- Key focus areas;

  -Training- job descriptions, resumes, effectiveness

  -Quality plans for implementing quality objectives

  -Mock MDSAP audits/ gap assessments

  -Off site documentation storage

  -System demonstrations/ software validations.

CardinalHealth
Essential to care™

Logistics
Product
Business
Patient

Thank you

CardinalHealth
Essential to care™

intertek
Total Quality. Assured.

MDSAP:
AN AO PERSPECTIVE

Presented by: Alexander Crosby
Americas Medical Program Manager,
Intertek Business Assurance

Intertek Business Assurance

COMMON MISUNDERSTANDINGS (1)

- Not all products distributed in each jurisdiction need to be cover in scope of MDSAP certificate
- Regulatory requirements do not need to be addressed by documented processes.
- This is a FDA-centric program
- The is a Health Canada-centric program and the application of a CMDCAS mentality to MDSAP
  - Only applicable to higher risk class devices (i.e. Class 2 and above in Canada)
  - Design is out of scope for lower risk device
- Australian Sponsor and/or Brazilian Importer and/or Japanese MAH are responsible for meeting all requirements not the manufacturer.
  - European EC Certificate is all that is necessary to meet Australian Requirements
  - MDD essential requirement are the same as to Australian essential principles

COMMON MISUNDERSTANDINGS (2)

- Audit plans can be revised and processes can be moved around to accommodate on-site issue.
- We can provide an definitive three year forecast of audit timing
- Sampling selection & audit & product coverage same as prior audits (auditor discretion.)
- Which locations are within scope
- The purpose, use and “value” of accredited certificates vs. MDSAP RA recognized certificates

MANUFACTURERS' CHALLENGES

- Underestimating level of effort and cost required for adequate preparation, in particular, address of regulatory requirements in the management system.
    - Be realistic about market expectations (i.e. When you expect launch products in new markets allowed by MDSAP, link product specific timelines to intent to market in each jurisdiction selected)
    - Unrealistic expectations of time to address areas of concern from stage 1
    - Inadequate detail in processes to address additional / new regulatory requirement (i.e. Treat all jurisdictions equally with specification of detail.)
- Not adequately addressing prior findings, thus getting repeat findings in your first MDSAP audit with impact on severity grading.
- Increased audit time often results in identification of non-conformities that were not encountered
- Absence of documented agreement with Australian sponsor and/or Brazilian importer and/or Japanese MAH
- Producing detailed relevant, timely, detailed information from virtual manufacturers in the language of the audit.

PREPARING FOR MDSAP (1)

Be prepared to expertly demonstrate that you have satisfied all regulatory requirements applicable to your devices, including:

- Regulatory roles per jurisdiction
- Device classification
- Market clearance
- Change notification
- Reporting device adverse event and field corrective action/recalls

PREPARING FOR MDSAP (2)

- Understand the scope and context for the upcoming MDSAP audit
  - If shipping medical devices to a MDSAP jurisdiction, country-specific requirements will apply
  - For multi-site operations, the sites that conduct activities for another site will be assessed per the requirements for the MDSAP cert
  - Intra-company support activities are subject to review of contracts, etc.. to verify coverage of audit requirements
- Use the QMS built into the QMS – internal audits, CAPA, management review, quality plans, etc.

TOTAL QUALITY. ASSURED.

- **Total Quality Assurance**
  end-to-end on a global scale
- **Global market leader in Assurance**
  3000+ Auditors, 100,000 Audits annually
- **Global market leader in Testing, Inspection and Certification**
  1,000+ sites, 100+ countries
- **Innovative and bespoke quality solutions**
  for our clients, 24/7
- **Constantly evolving our services**
  to help customers manage increasingly complex risks
- **FTSE 100 company**
  in the support services sector
- **Market capitalization**
  over £6 billion

13

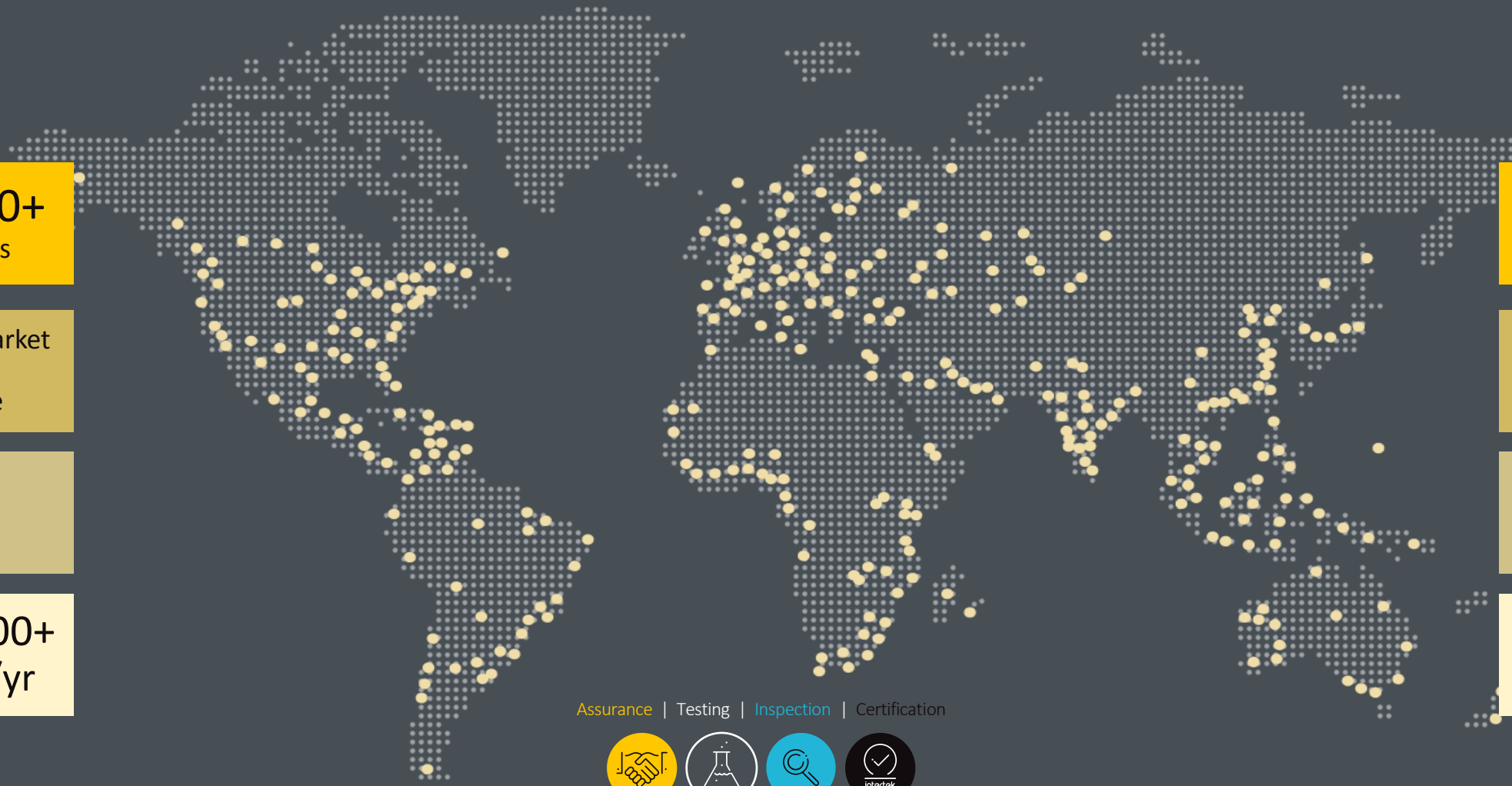
WE ARE UNIQUELY POSITIONED TO DELIVER ATIC SOLUTIONS WITH OUR GLOBAL NETWORK

43,000+
employees

Global Market Leader in Assurance

3,000
auditors

100,000+
audits/yr



100+
countries

Global Market Leader in TIC

1,000+
labs and offices

80+
languages

Assurance | Testing | Inspection | Certification

Systemic approach to Quality and Safety with ATIC Solutions

CONTACT INFORMATION

Alex Crosby

+1 (434) 242-4341

alexander.crosby@intertek.com

General Inquiries

+1 (800) 967-5352

business.assurance@intertek.com

Intertek.com/auditing/medical

intertek

Total Quality. Assured.