ISO9001:2015 Transition
Presented by
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Zenith Technologies:

• Founded 1998 by Brendan O’Regan
• Automation/Enterprise Systems Projects main business activity
• 650+ employees worldwide. Offices at Cork (HQ), Dublin, UK, Belgium, Germany, USA, Singapore, India

• First certified to ISO9001:2000 by NSAI in 2004
• Passed reassessment audit to ISO9001:2015 on 12-13 July 2016
Customers:

- Customer base is Pharmaceutical / Biotech regulated manufacturing
- Our customers expect a conservative approach to Quality
- Zenith QMS structure is traditional ISO9001 pyramid (Quality Policy, Quality Manual, Policies, Procedures, Work Instructions)
- 61 SOPs for Lifecycle and Support activities (Project Lifecycle V model) in accordance with the GAMP Guide
Key challenges for us:

- New concepts in Section 4 of the standard
- The ISO9001:2015 QMS questionnaire
  - What is the “context of the organisation”?
  - What are “Issues”? (Are all issues “risks”?)
  - Who are the “Interested Parties”?
- The Process Vs Clauses matrix
  - More detail needed in identification of processes (all processes need to be considered, even those which do not have an SOP)
  - Assigning objectives and risks to processes
  - Determine the scope of applicability of the QMS
How to migrate from the current system:

- How much of the old structure to retain?
- Do we need a Quality Manual?
- Is the Quality Policy still suitable?
- How to satisfy requirements of the standard, while still meeting customer (audit) expectations regarding the QMS?
Strategy adopted:

- New Quality Policy to better address an objectives framework and Plan-Do-Check-Act methodology
- New Quality Manual following the structure of the new standard, as per previous QMS structure. However, Section 4 has short explanatory paragraphs only, which refer heavily to the new “Context” and “Processes” and Risk Register documents.
- QMS “pyramid” structure to be retained.
- Adoption of a presentation format for use at strategic management meetings by Zenith top management. It includes columns for “Issues”, potential impact, response strategy, and budget impact.
Structure:

• New/modified in red
• Context, Risks and Processes documents sit next to QM
• KPI’s and metrics to be integrated into business/finance systems as “documented information”
Quality Policy:

• New Quality Policy to better address an objectives framework and Plan-Do-Check-Act methodology
Updated Quality Manual:

• Same structure as the standard
• Section 4 explains approach and references new documents

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Context of the Organisation:

- Context – who are we, what are our main objectives, what products and services do we supply, what environment(s) do we operate in
- “Considerations” identified from various sources related to our context and include all issues to be considered. A subset of these are risks.

- Interested parties (“Stakeholders” as per PMBoK) include Zenith departments, Zenith staff as individuals, customers, suppliers, regulatory bodies/auditors, financial institutions.
Issues, risks and opportunities:

• Differentiation between Project-level risks, and QMS risks for the purpose of the risks and issues analysis

• Project risks continue to be handled via existing Project Risk Management SOP based on GAMP / PMBoK
KPIs and metrics as Documented Information:

• Alignment of effort between Zenith Quality, PMO and Business Systems departments.
  – Documented information as an output from PMO
• Key metrics and KPIs to be pulled from business systems wherever possible including HR personal performance data, project progress Vs targets, enterprise performance Vs targets
Result:

- Audit on 12-13 July was a pass
- New certification from 28 Aug 16
- Next steps:
  - Continue with monthly/quarterly Quality tracking via Dashboard
  - Management Review of Issues, Risk Register, QMS effectiveness