









ISO9001:2015 Transition
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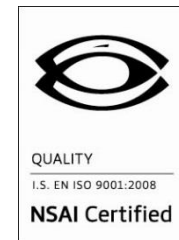
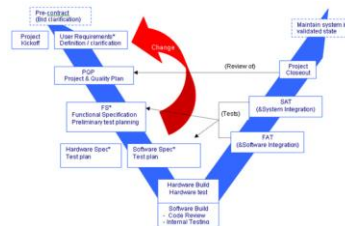
Delivering Automation, Process Control and MES Excellence

- 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?

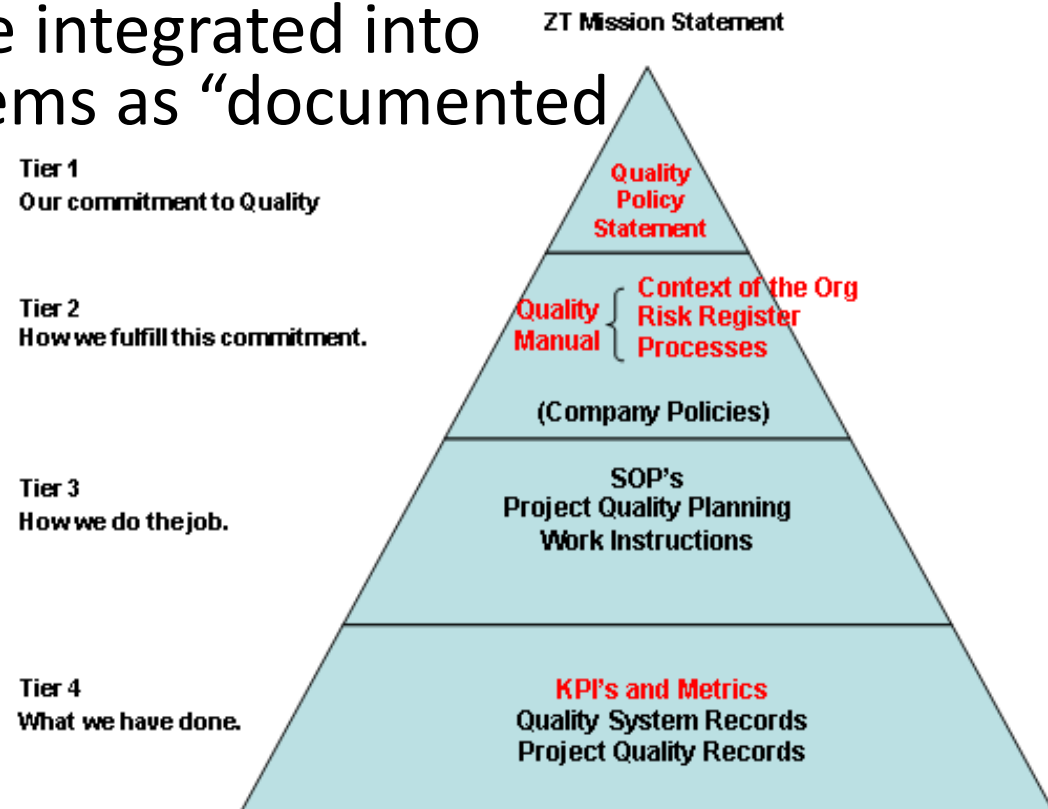
Strategy adopted:

- 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.
- New documents for ISO9001:2015: Context of the Organisation, Risk Register, Process Analysis.
- 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.

Regional Strategy 2015-18			
Consideration	Business Implications	Response Strategy	Budget Impact
Ability to satisfy demand	Missed targets. Disappointing Client expectations Damaged reputation	Accelerate development programmes for new hires. Proactively curle engineers between sites	Investment costs.

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



Our **Leadership Team** is committed to achieving excellence in Enterprise Systems by maintaining a Quality Management System in accordance with ISO 9001:2015. We will base this approach on our systems, our people, our customer focus and continual improvement of our processes in order to attain our strategic objectives.

Our Systems

We understand our business environment and we are proactive in defining our Processes in the context of our Global organization. We identify risks and opportunities and adapt our strategies accordingly. We do this both to increase our efficiency and to maintain the flexibility to adapt to our customers' needs.

Our People

Zenith's most important resource is its People. We are committed to creating an organisational culture that is inclusive, values leadership and teamwork and contributes to individual development. All team members are encouraged and empowered to engage with our quality processes and contribute meaningfully to improving



Customer Focus

We are committed to total Customer Satisfaction. We engage with our customers worldwide in order to fully understand their current and future needs. We are dedicated to providing solutions that will meet or exceed expectations for functionality, quality and value.

Continuous Improvement

We set goals and objectives and establish metrics of our performance against these in order to continuously improve our service to the customer. Key decisions are based on data gathered at audits, management reviews and feedback from our customers.

Updated Quality Manual:

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

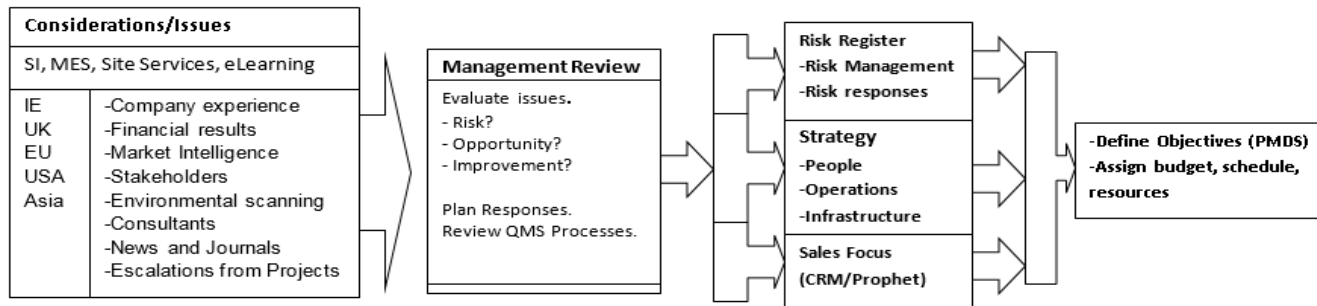
	Quality Manual	Doc I.D: ZQAL-001
		Revision: 7
		Effective date: 26Aug16
		Last review: 26Aug16

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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