ISO 9001:2015 Where to begin?

- Review the new standard
- Identify what gaps exist within your current system (if any)
- **Engage leadership** & plan actions to address these gaps
- Implement changes where necessary
4.1 Understanding the organisation and its context

• What are the external issues that are relevant to the organisation and the quality management system?

• What are the internal issues that are relevant to the organisation and the quality management system?

• These issues should be monitored and reviewed on a regular basis

• Document the issues and their potential impact to the business i.e. what risks or opportunities do they pose?
Clause 4: Context of the Organisation

4.2 Understanding the needs & expectations of interested parties

- Identify who the interested parties are that are relevant to the Quality Management System.
- What are their requirements, needs & expectations?
- Interested parties and their needs & expectations need to be identified and reviewed regularly as they may be dynamic and change over time.
- Document these as part of brainstorming sessions / management meetings.

<table>
<thead>
<tr>
<th>Interested Party</th>
<th>Needs &amp; Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customers</td>
<td>Quality, Price, Delivery</td>
</tr>
<tr>
<td>Regulatory Bodies</td>
<td>Compliance to requirements</td>
</tr>
<tr>
<td>Employees</td>
<td>Good Work Environment, Job Security, Career Development</td>
</tr>
<tr>
<td>Management</td>
<td>Business Growth, performance etc.</td>
</tr>
</tbody>
</table>
Clause 4: Context of the Organisation

4.3 Determining the scope of the quality management system

- The information gathered in clause 4.1 & 4.2 needs to be considered when determining the scope of your quality management system.

- Make reference to evidence of the reviews of the issues identified in clause 4.1 & 4.2 in the scope document.

- The scope should state the products / services provided and also list all applicable sites / locations.

Scope of QMS
Clause 4: Context of the Organisation

4.4 Quality management system & its processes

• Identify the processes that are relevant to your quality management system

• Determine what the inputs & expected outputs are

• Demonstrate their sequence & interaction

• What resources are required?

• How to monitor and measure the effectiveness of the processes?

• Are there risks & opportunities associated with the processes?

• Can processes be improved?
Risk Based Thinking

• Identify risks and opportunities that can impact your business, these may be linked with the issues identified in clause 4.1 & 4.2

• Plan actions to address the risks and opportunities that may impact your business

• Implement actions & monitor the effectiveness of actions taken

• Risk based thinking is not new, it is probably something you already do

• Formal risk management is not specifically required
Leadership

- There is a greater emphasis on Leadership and Management commitment in ISO 9001:2015
- Engagement of Top Management is essential for a successful transition
- Context, interested parties, assessment of risks & opportunities fits in with the needs of Top Management
- No longer a specific requirement for a Management Representative
• Transitioning to ISO 9001:2015 does not necessarily mean a complete overhaul of your existing quality management system

• If you are upgrading an already effective system then the changes may be minimal

• If it works for your business keep it!

• Many of the changes are not completely new and may be something that you are doing already!

• If you haven’t already started planning the transition, start today!