

# Implementing ISO15189

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## Presentation Goals

- **Provide candid and valuable perspective of experiences and lessons learned on implementing a Quality Management System to meet recognized standards, and,**
- **Some advantages that a Quality Management System provides in preparing for further initiatives, such as *LEAN***

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# Learning Objectives

- ✍ **Getting Started**
- ✍ **The People**
- ✍ **The Vision**
- ✍ **The Plan**
- ✍ **Moving forward**
- ✍ **Are we done yet?**
- ✍ **Maintenance**
- ✍ **Assessment & Improvement**

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By the End of this Presentation,  
attendees will have heard that:

- ✍ **Implementing QMS using ISO 15189 is about changing your Laboratory's Life Style**
- ✍ **Success depends on:**
  - Learning
  - Training
  - Patience
  - Persistence
  - A Robust Plan

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## Getting Started

- ✍ **OMG !!! What now?**
- ✍ **Why this, on top of everything else?**
- ✍ **Start with Learning, Training and Patience**
- ✍ **What is a Quality Management System?**
- ✍ **What is ISO 15189?**
- ✍ **What are the compelling reasons for a QMS?**
- ✍ **Who needs to be involved?**
- ✍ **What resources do we need?**
- ✍ **What resources are available?**

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## Ontario Laboratory Accreditation

- ✍ **Mandated accreditation**
- ✍ **License to operate, funding**
- ✍ **[www.qmpls.org](http://www.qmpls.org)**
- ✍ **Guidance, tools, education**
- ✍ **Assessor training**
- ✍ **Committees**
- ✍ **Knowledgeable Leadership**
- ✍ **Explicit instructions**

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## The People

- ✍ **Need a credible Champion**
- ✍ **Need a committed QM supported by Leaders**
- ✍ **Gain knowledge of QMS and advocate for QMS**
- ✍ **Understand meaning of ISO 15189 standards**
- ✍ **Personally willing to make a fundamental shift**
- ✍ **Can lead, train, relay information and guide others**
- ✍ **Patience, endurance, tolerance, staying power**
- ✍ **Sit down together and develop a “strategy”**

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## The Vision

- ✍ **Strategy session should include The Vision**
- ✍ **Building the compelling reason is not easy**
- ✍ **Helpful if QMS is mandated**
- ✍ **Even better if ISO 15189 is the requirement**
- ✍ **State assumptions about necessary resources**
- ✍ **Build justification to support assumptions**
- ✍ **Sell your strategy, get Buy In**
- ✍ **Take what you can get and move on!**

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## The Plan

- ✍ **Communicate The Vision**
- ✍ **Build understanding – changing culture**
- ✍ **High Level Plan – What do we need to do?**
- ✍ **Where is the best starting point?**
  - Quality Manual
  - Document Control
- ✍ **Gap Analysis – What do we already have?**
  - Inventory
- ✍ **Project Planning 101 – Map the “to do list”**
- ✍ **Process mapping and Procedures**

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## Moving Forward

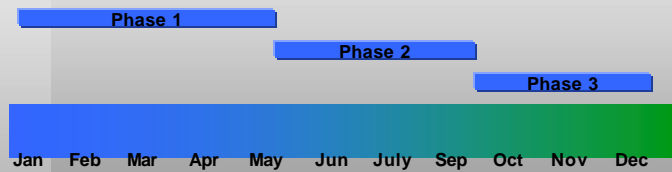
- ✍ **You can only do what you can do!**
- ✍ **Having said that, don't stop moving**
- ✍ **Assign responsibilities – the 'to do list'**
- ✍ **Support for the committed – tools, information**
- ✍ **What are realistic milestones?**
- ✍ **Draw a schedule**
- ✍ **Come together frequently for progress updates**
- ✍ **Communicate frequently, even if just a little**

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# High Level Plan

## High-level milestones:



FOR MORE INFO...

Quality Management Program – Laboratory Services (QMP-LS, OLA)  
Clinical and Laboratory Standards Institute (CLSI)  
ISO 15189

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# Quality Manual

- ✍ Provides the QMS “road map” through policy statements
- ✍ Explains what is included in the QMS and where to find the proof
- ✍ Refer to or include management processes and procedures
- ✍ Refer to technical processes and procedures
- ✍ Refer to supporting documents, records
- ✍ Need for Staff to be familiar and understand

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## Are we done yet?

- ✍ **Process Mapping**
  - Involve staff
  - Validate
- ✍ **Procedures**
- ✍ **Corrections, changes to old and new ones**
- ✍ **Processes – lot's of new ones**
- ✍ **Inevitably, improvement ideas surface**
  - Now or wait until later?
- ✍ **Conflict – standardization is a great concept!**
- ✍ **Cultural shift is not easy**

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## Maintenance

- ✍ **Explaining, teaching, reminding, perseverance**
- ✍ **Staff review and sign-off**
- ✍ **Implementing new or changed processes**
  - Monitor and document
- ✍ **Developing review schedules – who, when**
- ✍ **If it isn't documented, it didn't happen!**
- ✍ **Incorporate requirements into performance expectations**
- ✍ **Reward staff as QM becomes "routine"**

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## Assessment and Improvement

- ✍ Improved processes that had been deferred
- ✍ Notice of Self-Assessment
- ✍ Few 'majors', lots of minors
- ✍ Built a plan to correct
- ✍ Enthusiasm starting to 'flag a little'
- ✍ Staff can't remember what QMS stands for
- ✍ Leadership becomes paramount
- ✍ Build on The Vision – share the indicators that demonstrate improvement, value

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## Advantages beyond Quality

- ✍ Lab staff better understand process improvement
- ✍ Lab staff are more engaged with their customer
- ✍ Lab staff are more confident in their ability to talk about what they do and why
- ✍ Lab staff are more capable in expressing improvement ideas
- ✍ Lab staff are more willing to participate in improvement initiatives
- ✍ Sense of overall pride, accomplishment

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