



2009 QNET Excellence Conference – GET FOCUSED

Quality & Effectiveness

Steady Steering

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Strategic Operations Planning™

The missing link between the strategic business plan and results

Presented by:
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Quality

Let's Deal with the Issues

“I was in a warm bed and suddenly I’m a part of a plan.”

- Woody Allen in *Shadows and Fog*.

There in lies every argument against strategic planning.

“It’s extremely hard to get executives to do strategic planning. Strategic planning is very mentally challenging”

- Former Chairman and CEO of the largest vaccine manufacturer in the world.



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Quality

Let's Deal with the Issues

When strategic planning fails, it's for one or more of the obvious reasons:

No method was used.

No proven method was used. (a lot of flawed “credible” methods)

Where do you want to be when?

The method was incomplete – SBP vs. SOP

The method wasn't understood or followed correctly.

The effort was half hearted

The resulting plan was never implemented (started or completed)

The resulting plan was not continuously updated.



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Reality Sinks In

Karrass course on “Effective Negotiating”

First on the list of factors – “The Power of Planning”

An exercise conducted at all training sessions:

Team A – No planning

Team B – Some planning

Team C – Most planning

The distribution of wins & loses is as you would expect

Team A has never beaten Team C!



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Reality Sinks In

Michael Phelps - With **14** gold medals in his Olympic career, he's now alone in the history books -- he has won more gold medals than anyone else in Olympic history and more gold medals than anyone else in any single Games

His coach, Bowman, who is something of a student of success literature, said it's a result of Michael's hard work, determination, and planning. "Successful people make a habit of doing things that unsuccessful people don't like to do."

Tiger Woods – When asked if he focused on visualizing the ball going into the hole when he stood over a put, he replied: "No. I focus only on the process. If I get the process right, the ball will go into the hole."



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Strategic Planning & Regulatory Compliance

Current Standards – Recent Changes

- ICH Q10 - PHARMACEUTICAL QUALITY SYSTEM, Current Step 4 Version - June 4, 2008.
 - Almost entirely devoted to executive and operations management responsibilities – “should be documented in the Quality System.”
 - This guideline represents a consensus of both regulatory and industry experts within the international community.
 - Is based on ISO quality concepts, includes applicable Good Manufacturing Practice (GMP) regulations and complements ICH Q8 “Pharmaceutical Development” and ICH Q9 “Quality Risk Management”.



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Strategic Planning & Regulatory Compliance

Current Standards – Recent changes (cont'd)

- FDA Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations – 6452, September 2006.
 - “An effective approach” (if not necessary)
 - Compliance is substantially dependent on executive and operations management functions (roles & responsibilities)
 - Management functions are “an essential part of a contemporary and effective Quality System”



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Strategic Planning & Regulatory Compliance

Current Standards – Recent changes (cont'd)

Planning, Prioritization, and Communication

- “Quality system plans (strategic operations plan™) should be aligned with a manufacturer’s strategic plans (strategic business plan) to ensure that the system is part of the manufacturer’s mission and quality strategies.”
- “Senior managers set implementation priorities and develop action plans.”



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Assessments of top Biopharmaceutical Companies

Planning, Prioritization, and Communication

- **Problem:** There are no defined processes for these functions - Inadequate development, communication, and implementation of business and operations strategies, priorities, and specific action plans – personnel dissatisfaction
- **Solution:** Adopt a formal and integrated process for Business and Strategic Operations Planning™ and formalize communication processes



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Strategic Operations Planning

Strategic Operations Planning™ Benefits

- Clarifies unique roles or mission for each department or operating unit.
- Is a comprehensive account and reconciliation of routine operations as well as special projects and aligns them with goals and objectives - (why?).
- Identifies & differentiates the functionality and factors that are strategic to optimizing outcomes.



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Strategic Operations Planning

Strategic Operations Planning™ Benefits

- Reconciles the roles and responsibilities within the organization which avoids duplication of effort and assures integration across all departments and operating units.
- Improves everyone's grasp of how the entire organization can best achieve the results it desires.
- Enhances everyone's focus on priorities and understanding of where to start and how to proceed.



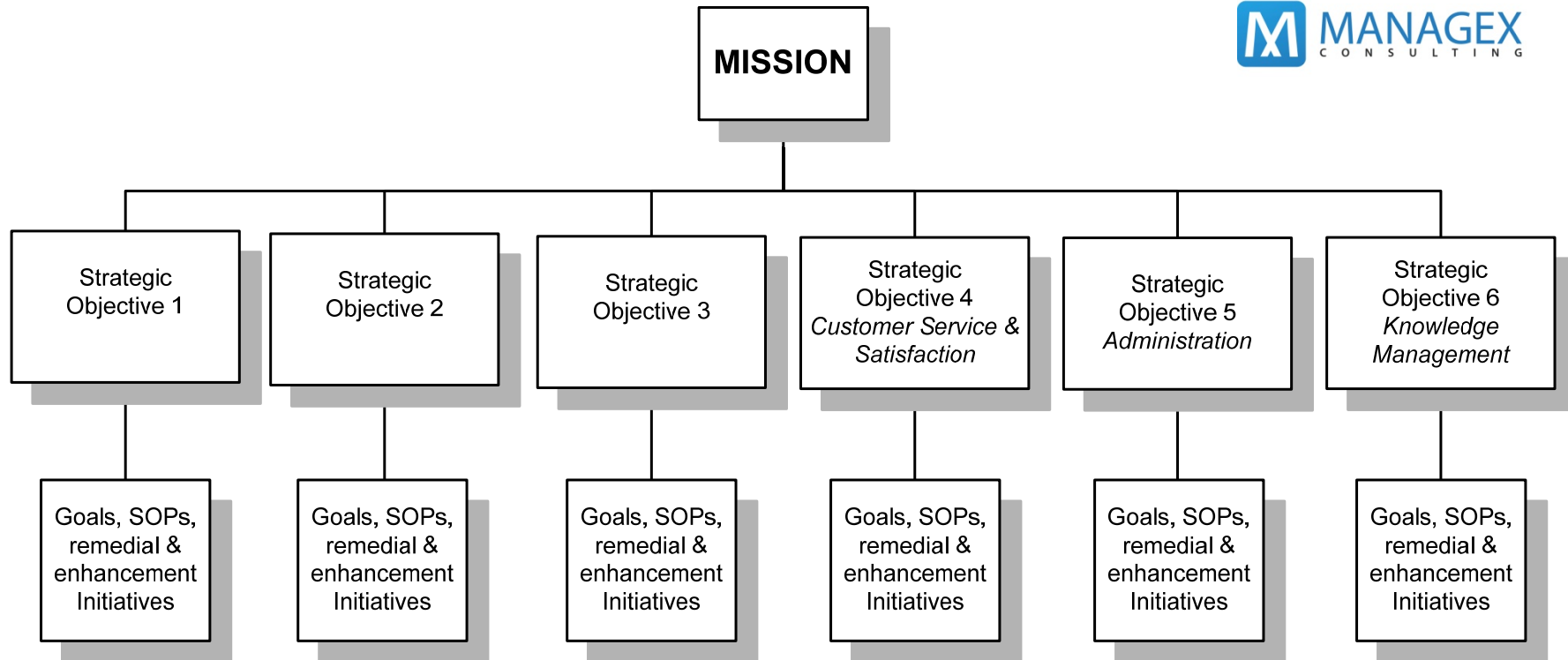
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Quality

Strategic Operations Planning

Operating Unit Strategic Operations Plan
_____ Corporation



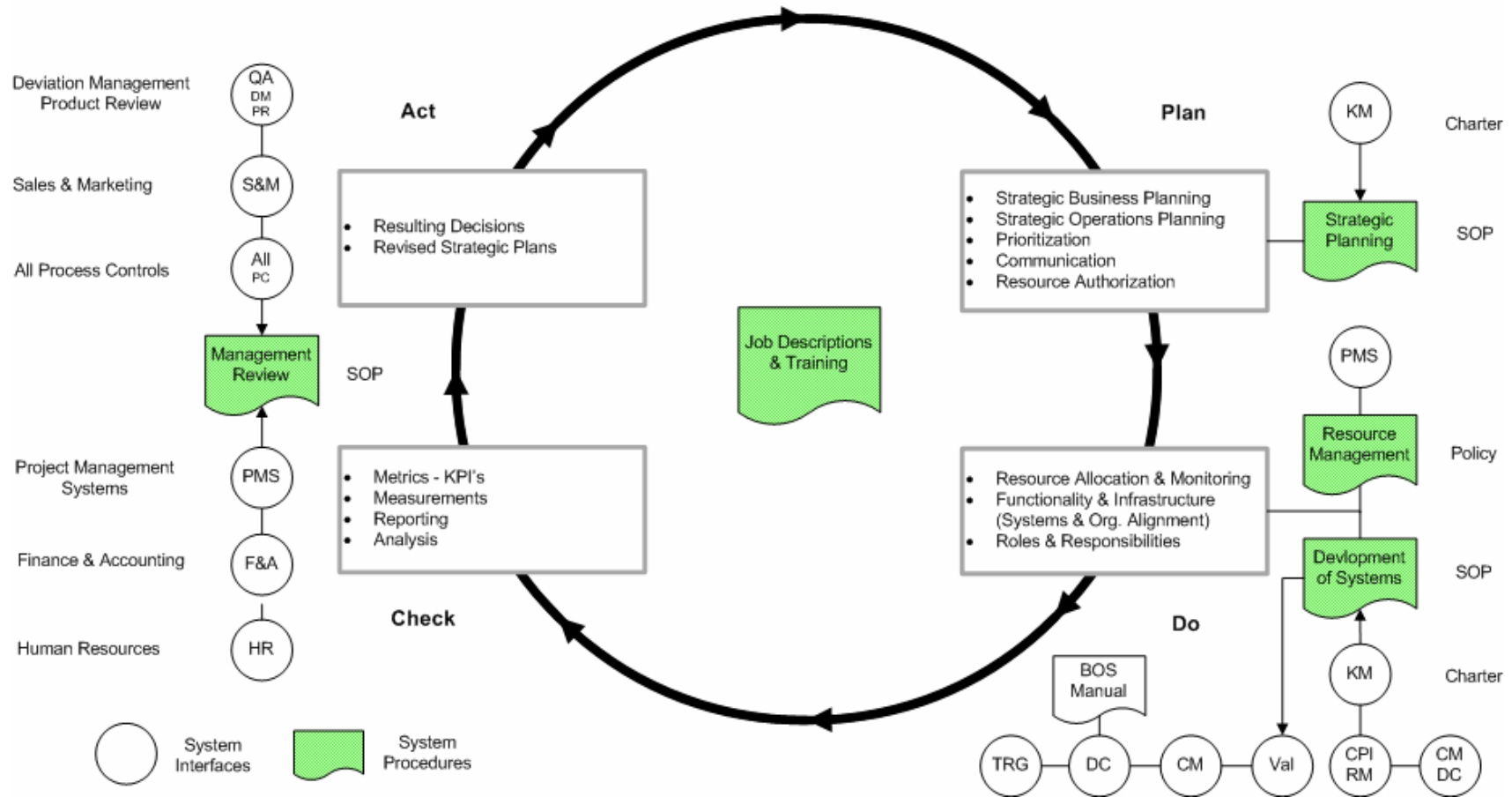
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The "M" System - Delivered

The Management System Cycle



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Wrong Answer

THE GREATEST RISK IS NOT TAKING ONE.SM

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Magazine
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Tools

- Summary notes available at www.qnet.mb.ca
- Contact **Dr. Michel Tétreault**, President and CEO, St. Boniface General Hospital at (email@email.com and/or (204) 237-2340)
- Contact **Thomas Feyerabend**, President, MANAGEX Consulting at (tfeyerabend@managexconsulting.com and/or (816) 896-1030)
- Contact **Michael Easton**, Vice President Manufacturing, Argus Industries at (mike@argusindustries.ca and/or (204) 837-4660)

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