Navigating a QMS Integration – A Road Map through the Trenches

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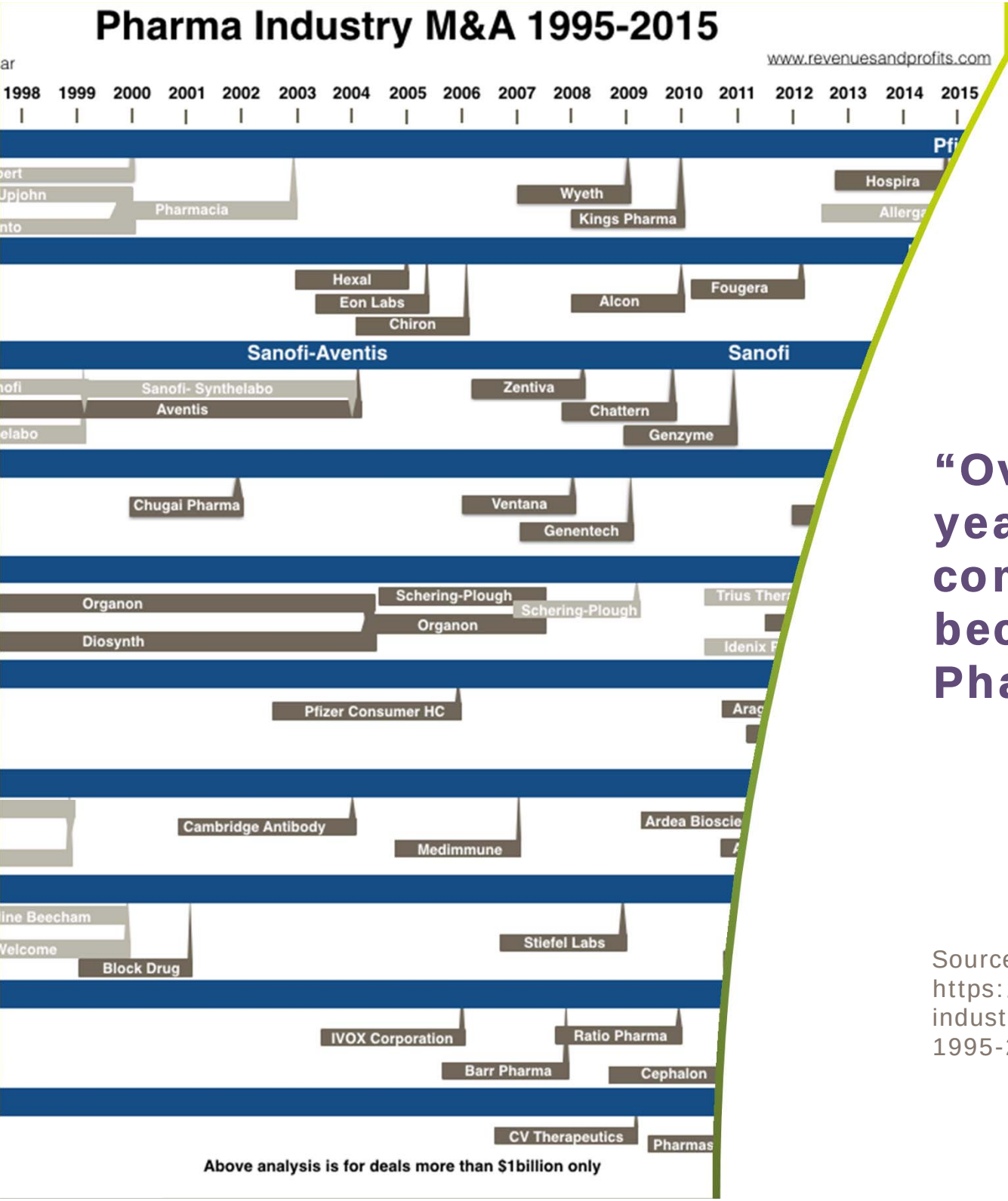


“Over the last 20 years, 60 Pharma companies have become 10 Big Pharma companies.”

Source: https://revenuesandprofits.com/pharma-industry-merger-and-acquisition-analysis-1995-2015/

Integration is….

- **A means to:**
- Acquire new products and technologies
- Expand into new geographic areas
- Divest portions of product portfolio
- Acquire capacity and resources (equipment and people)

- **Complex:**
- Organizational complexity
- Geographic complexity
- Infrastructure/technology complexity

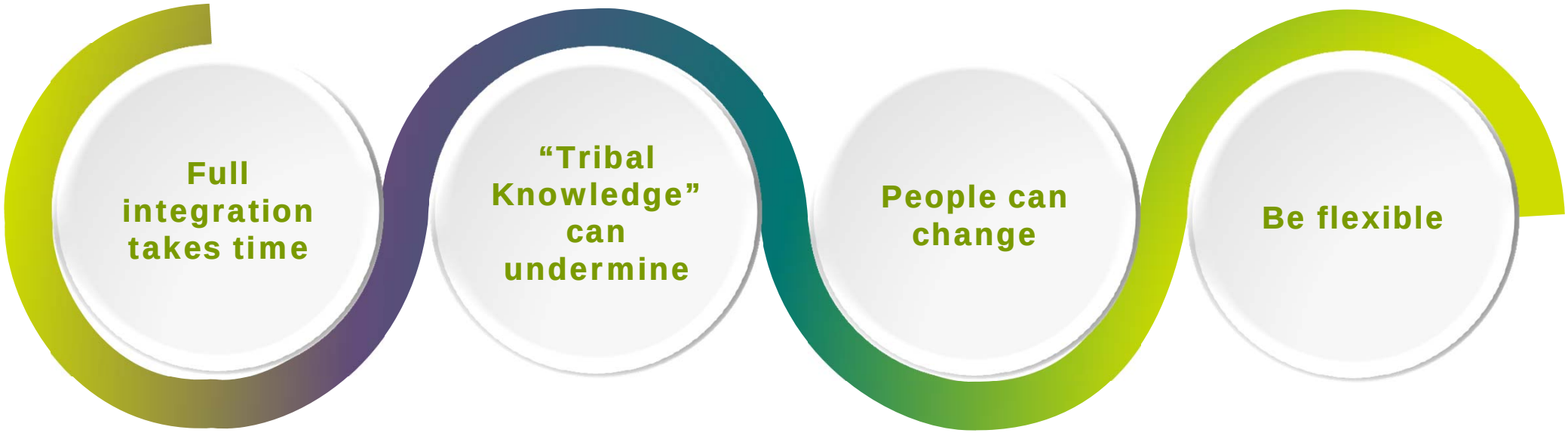
Is it processes?

What is QMS?

Is it people?

My story

Lessons I’ve learned



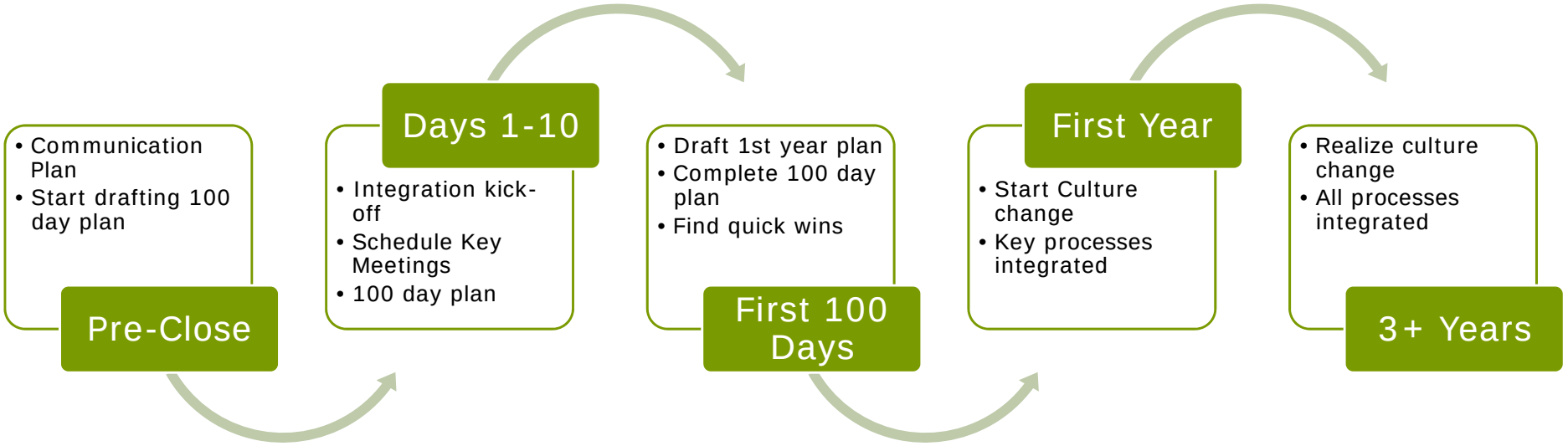
- Often underestimated
- Often rushed
- Often siloed

- Processes not reflective of “actual”
- Risk loosing with staff reductions

- Takes effort
- Can be a morale killer

- What you know on day one
  <
  what you know on day 100

Major milestones



Communicate, Communicate, Communicate

Key Factors in a Successful QMS Integration

Communication

- Types (face to face, email, written, video boards, etc.)
- Frequency
- Key Messages
- FAQs

Decision Authority

- Who can make what decisions -> matrix
- Minimize disruptions initially

Project Management

- QMS one of many work streams
- Interface points and interdependencies
- Escalation
- Routine reporting

Quality & Regulatory

Subject	Task	Complete	5-Dec	12-Dec	19-Dec	26-Dec	2-Jan	9-Jan	16-Jan	23-Jan	30-Jan	6-Feb	13-Feb	20-Feb	27-Feb	End Q1	End Q2	End Q3	End Q4	Effort (FTE): Low: <= 40 hrs Med: <= 160 hrs High: > 160 hrs	Additional Team Members
GMP Compliance audit	Complete	X																		Low	Plant Staff, Reg
QMS Integration/Improvements																					
a. Design History Files	SOP revisions																			High	
	Locate and organize current files		!																		
	Update and Correct existing files		!																		
	Prepare annual updates for FDA filings		!																		
	Establish procedure to ensure annual FDA requirements will be completed annually																				
	Review process for managing Letters of Authorization																				
b. Validation Master Plan	Update documents and policy;																			High	
	Update SOP for validations: computer systems, cleaning, process validation, sterilization																				
	Develop schedule to assess GMP system validation packages and plan for revalidation																				
c. Warehouse and Storage	Revise SOP for product stability to include storage conditions (temp, RH, etc)																			Med - High	
	Evaluate container-closure integrity and/or other factors that would trigger reassessment of product stability.																				
	Storage space assessment: Layout of current on-site storage and capacity, Document procedures and requirements for off-site storage conditions																				
d. Material Release and OOS review	Revise policy and documentation related to dispositioning of out of spec material, for authority to QA not the MRB		!																	Med	
	Review and Update the Batch Release Procedures																				
e. Device Master Records	Update SOP and templates to include all required information: Consistent with DMR and 211 requirements																			Me	
f. Device History Records	Revise SOP and templates to include all required information, consistent with DHR and 211 requirements																				
	Develop product-specific forms for each product type														PLA						
g. Change Approvals	Review procedures for updating																				
	Conduct a review of change requests for last 2 years for proper approvals.																				
	Schedule plant-wide training on change approval																				
h. Corrective and Preventative Actions	Transfer responsibility from MRB to Quality.																				
	Update procedures and review meetings																				
	Develop plan for improved investigation techniques																				
ISO and Quality Audits																					
Regularly scheduled ISO surveillance audit								ISO													
On-going customer audits - by request																					
CE Marking																					
Understand marketing requirements by product																					
Attend webinar or training on CE requirements for these products																					
Requires that Device Master Files and Design History information be corrected and updated (above)																					
Develop schedule for filing with authorized agent																					
CE Mark Registration																tbd	tbd	tbd			
Product Specifications and Claims																					
Review certificates and external claims																					
Review testing methods and data accuracy																	50%	100%			
Assess regulatory filing requirements																					
2012 YE Plan	Review data to determine plans for rest of year																				
Review current Quality and Production data systems	CAPAs, internal audits																				
	Customer complaints, audits																				
	Non-conforming or OOS trends																				

delay customer requests

100 Day Plan

Prioritizes work

Visual

100 Day "Quick Reference"

December

- Closing
- Welcome to Company ACB
- Integration Kickoff
- 100 Day Plans
- Integration Reporting Commence
- Sales Integration Plan
- Financial Integration "Month 1 Closing"

January

- Plan for Int'l Launches
- ISO Audit
- Leadership Visit
- Intellectual Property Training
- "Wave 1" Laptops
- EHS Assessments
- Near Term Inventory Plan
- Brand Plan
- Info Security Audit

February

- Code of Conduct / Values Rollout
- Comp & Ben Integration Plan
- Sarbox "Health Check"
- PeopleSoft Fin & HR Plan
- IT Infrastructure Design
- Batch System Tech Assessment
- Procurement Spend Analysis
- 2012 Integration Plans

March

- Sales Force Meeting / Training
- Sales Force Integration
- Product Launch(es)?
- EHS Wave 1 Action Plans

Prioritize and Visualize

Work Stream Considerations

- **Co-Leads by major QMS system**
- **Clear Roles and responsibilities**

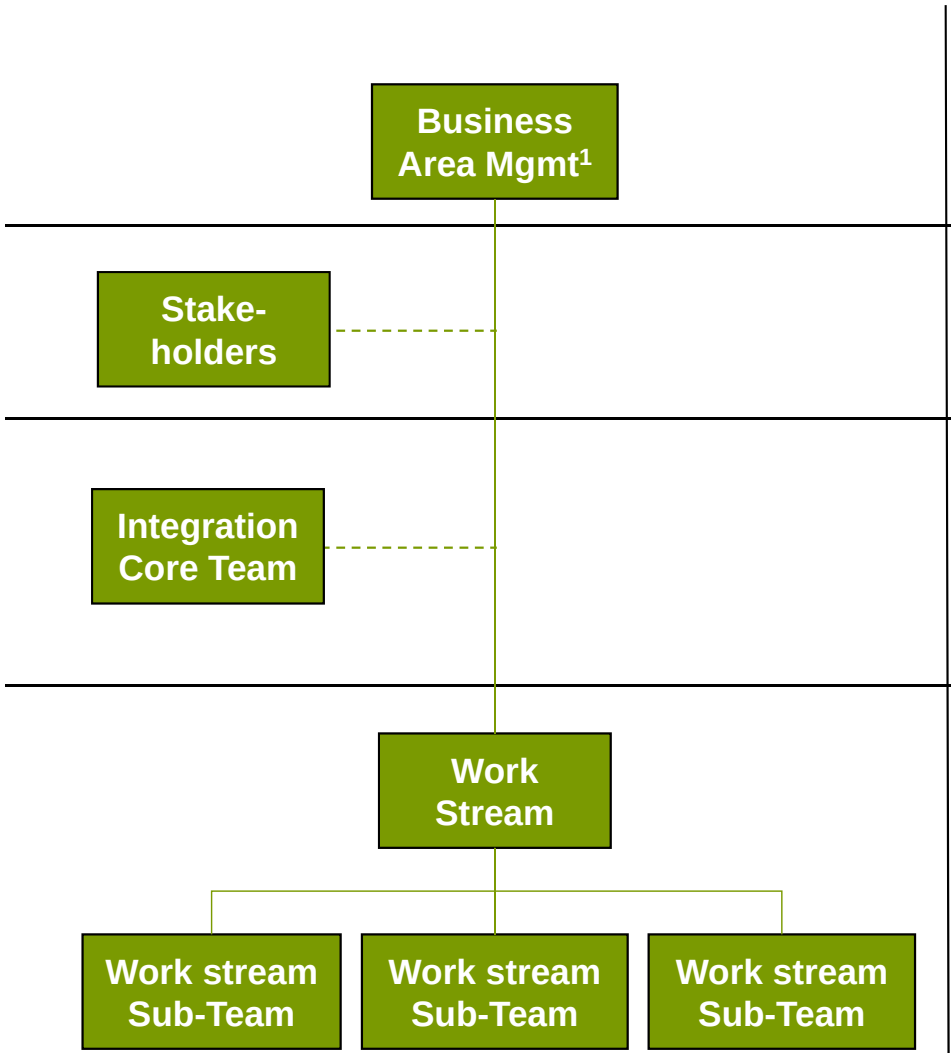
Work stream leads

- Develop and execute a functional vision and integration plan prioritizing mission critical items
- Deliver functional integration objectives
- Obtain appropriate resources to ensure successful execution
- Establish a “governance” structure with functional stakeholders. Gain & maintain their support. Keep them informed.
- Serve as a member of the Integration Core Team

Stakeholders

- Approve the functional vision and integration plan
- Approve prioritization of functional work activities
- Obtain appropriate resources to ensure successful execution
- Provide input, guidance and feedback

Decision Authority



- Approve functional visions
- Approve functional work activities to be accomplished
- Approve work activity prioritization

- Approve2 functional vision
- Approve2 functional work activities to be accomplished
- Approve2 functional work activity prioritization

- Prioritize work activities across functions
- Allocate resources to work activities across functions
- Define integration program approach and methodology
- Approve program results / scoring

- Define functional vision:
- Define functional work activities to be accomplished
- Prioritize work activities within function
- Allocate resources to work activities within function

[1] And appropriate corporate staff, depending upon decision
[2] or “inform”, depending upon role of stakeholders

Engagement Principles

DON'Ts

- ✓ Avoid using
  - "Here's how we do it at …." or
  - "We've always done it this way" or
  - "We've never had an issue on….with ….regulatory agency"
- ✓ Be a General or an "order giver"
- ✓ Escalate decisions without engagement & support of co-lead
- ✓ Descend upon site in large groups

Team Communication Cadence

Full Integration Team Meetings (monthly)	Length: 1-2 hours Purpose: Program communications, key issues, cross-functional dialog
Work Stream Status Meetings (weekly or bi-weekly)	Length: 20 minutes (hard stop) Purpose: Ensure progress on work stream activities
Reporting Requirements	Status Report (weekly or bi-weekly) Integration Reporting (monthly)
SharePoint Site	Shared documents / files Program Calendar – key milestones identified

Status Reporting

[redacted] Integration – Quality Function

Status Report – July, 2012

Project Scoreboard

Bus Objectives	G
Schedule	G
Cost	G
Resources	Y
Issues	Y
Risk	Y

Key Accomplishments

Completed

- Launched new batch record format for Liquid production.
- Continued with multiple customer audits (July = 3).
- Implemented new labels and seals on catalog items.
- [redacted]
- [redacted]
- NCR and CAPA procedures implemented (no MRB)
- QM updates complete
- Deferred on-line labeling.

In process

- Reviewing Regulatory Plan to support [redacted]
- See upcoming events….

Key Upcoming Events (one month horizon)

- Customer Audit Scheduled: August (2)
- Standardize content for Supplier Quality Agreements
- Continued support for Production metrics, Custom product process streamlining
- Gowning procedures and train staff, scheduled 8/10
- Pilot Environmental monitoring and cleaning, beginning 7/30
- Complete [redacted] Validation, in process
- Recruit Quality Engineer

Issues & Concerns

- [redacted]
- **Branding Change on Products:** Timing of implementation for customers using custom products is uncertain pending review of actual branding change.
- **European product launch support:** The preliminary request for a Eu launch was to achieve CE and IVD Medical Device claims within [redacted]. Have reviewed the regulatory standards for Eu that will apply to custom products, and will require significant capital upgrades to meet customer expectations.
- **Update Supporting Documentation for Batch Records** – Availability of resources to support updating Manufacturing Instructions and Manufacturing Packaging Instructions.

Major Milestone Schedule

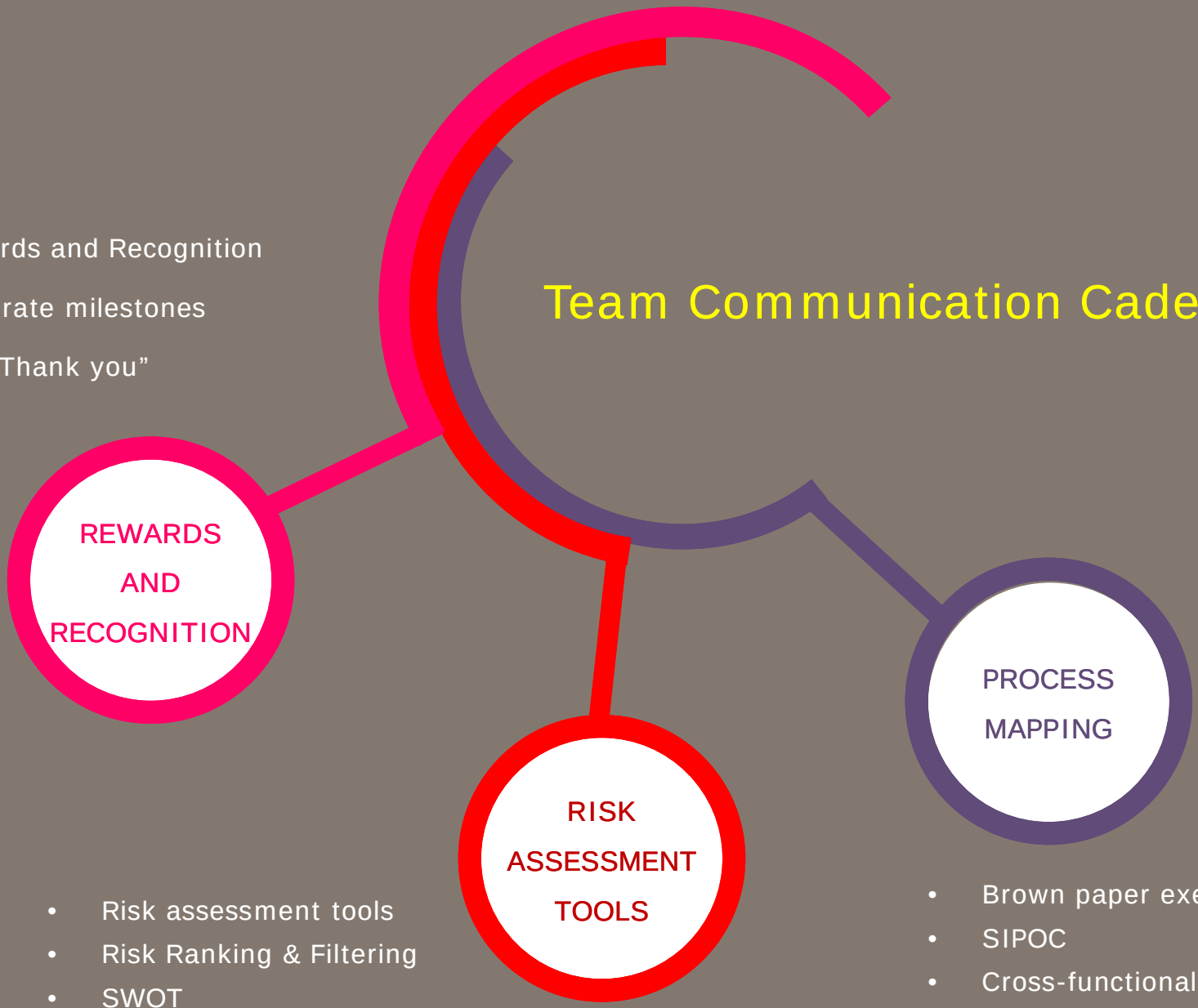
Key Activity - Full Year Plan	Start Date	End Date	% Done	
Validation Schedule Developed & Resourced	1/23/12	5/31/12	100%	✓
Batch Record System				✓
Pilot	3/1/12	4/15/12	100%	✓
Impl for Std Products	4/15/12	7/2/12	100%	✓
[redacted] Upgrade				
Execute Validation, Quote received	4/1/12	5/30/12	100%	✓
Go Live	6/30/12	7/31/12	70%	
Implement Branding Change on Products	3/15/12	8/31/12	90%	
Update Tech Service Standard Documentation	4/1/12	9/30/12	35%	
Develop Regulatory Filing Plan by Country	4/15/12	9/1/12	75%	

Integrating Culture

- **Expect 2-5 years for complete integration**
- **Requires up front investment and ongoing support**
- Education – values, behavioral norms
- Visual reminders – posters, video bulletin boards
- Ongoing coaching and mentoring
- Linking to performance management
- **Assessment methodologies**
- Surveys
- Conversations (town halls, skip level meetings, “coffee klatch”)
- Visualize using heat maps

Function	Culture dimension 1	Culture dimension 2	Culture dimension 3	Culture dimension 4	Culture dimension 5
R&D					
Sales					
QC					
QA					
Manufacturing					
Regulatory					

Team Communication Cadence



- Rewards and Recognition
- Celebrate milestones
- Say “Thank you”

- Risk assessment tools
- Risk Ranking & Filtering
- SWOT
- Risk matrices

- Brown paper exercises
- SIPOC
- Cross-functional flowcharts

Questions?

Thank you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Key Projects
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Find a position
See what we offer
Read our case studies