



Close Out Report

**Records Management and
Decommissioning Project at
Manufacturing Plant at Comazzo
(Italy)**

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Project Stages

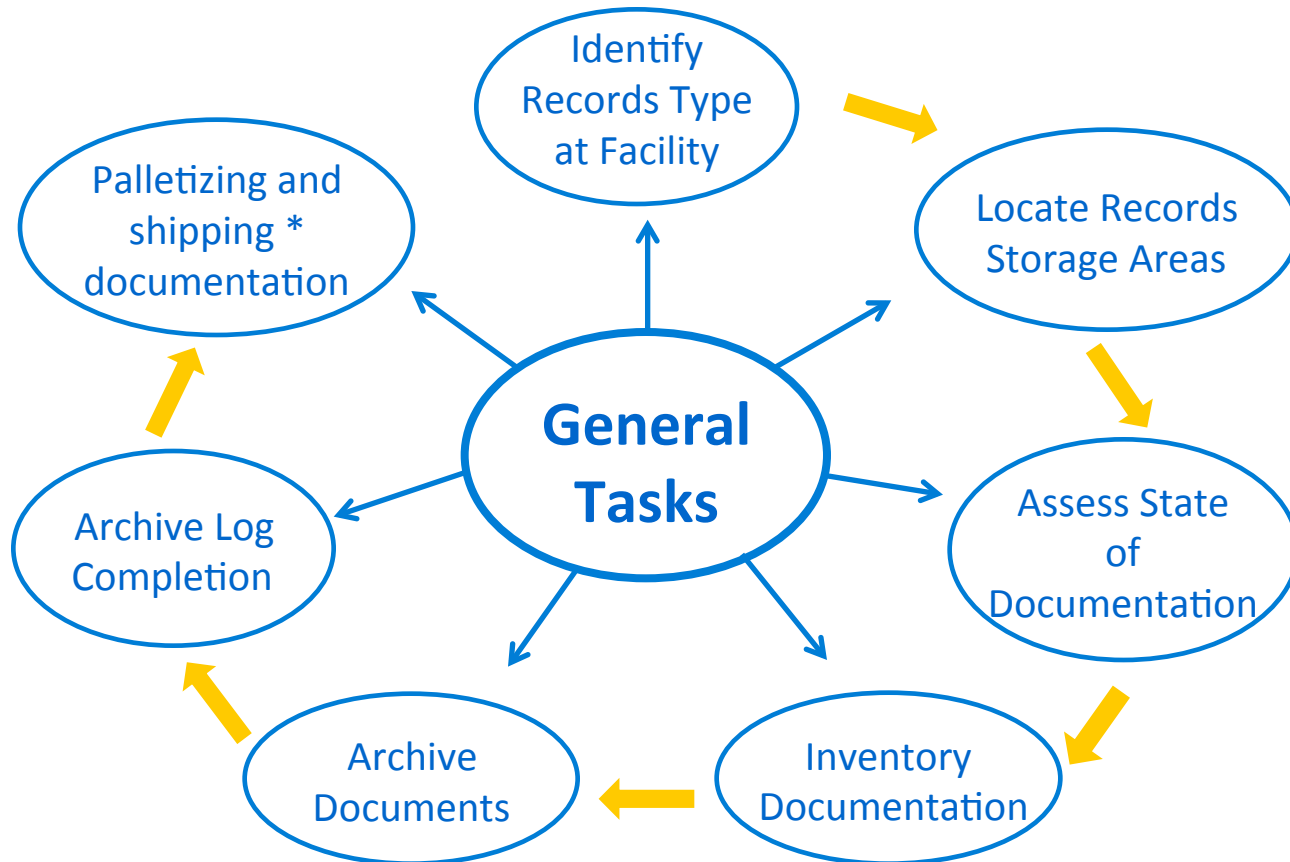
✓ Records Management

- Plant-Wide Documentation:
 - Batch Records
 - SLC documentation
 - Non GMP Records
- Samples:
 - Stability Samples
 - Retention Samples

✓ Decommissioning of GMP Equipment and Systems

- Quality
- Manufacturing
- Packaging
- Warehouse
- Utilities

Records Management: Plant-Wide Documentation



*EAD: External Archiving Documentation – MGM Outsourcing Documental Division

Records Management

Plant-Wide Documentation



Batch Records



- 2061 Binders Inventoried
- 500 Binders Destroyed
- 709 Boxes Shipped

SLC Documentation and Non GMP Records



- 6567 Binders
- 800 Binders Destroyed
- 2357 Boxes Shipped

Samples



Retention Samples

Stability Samples

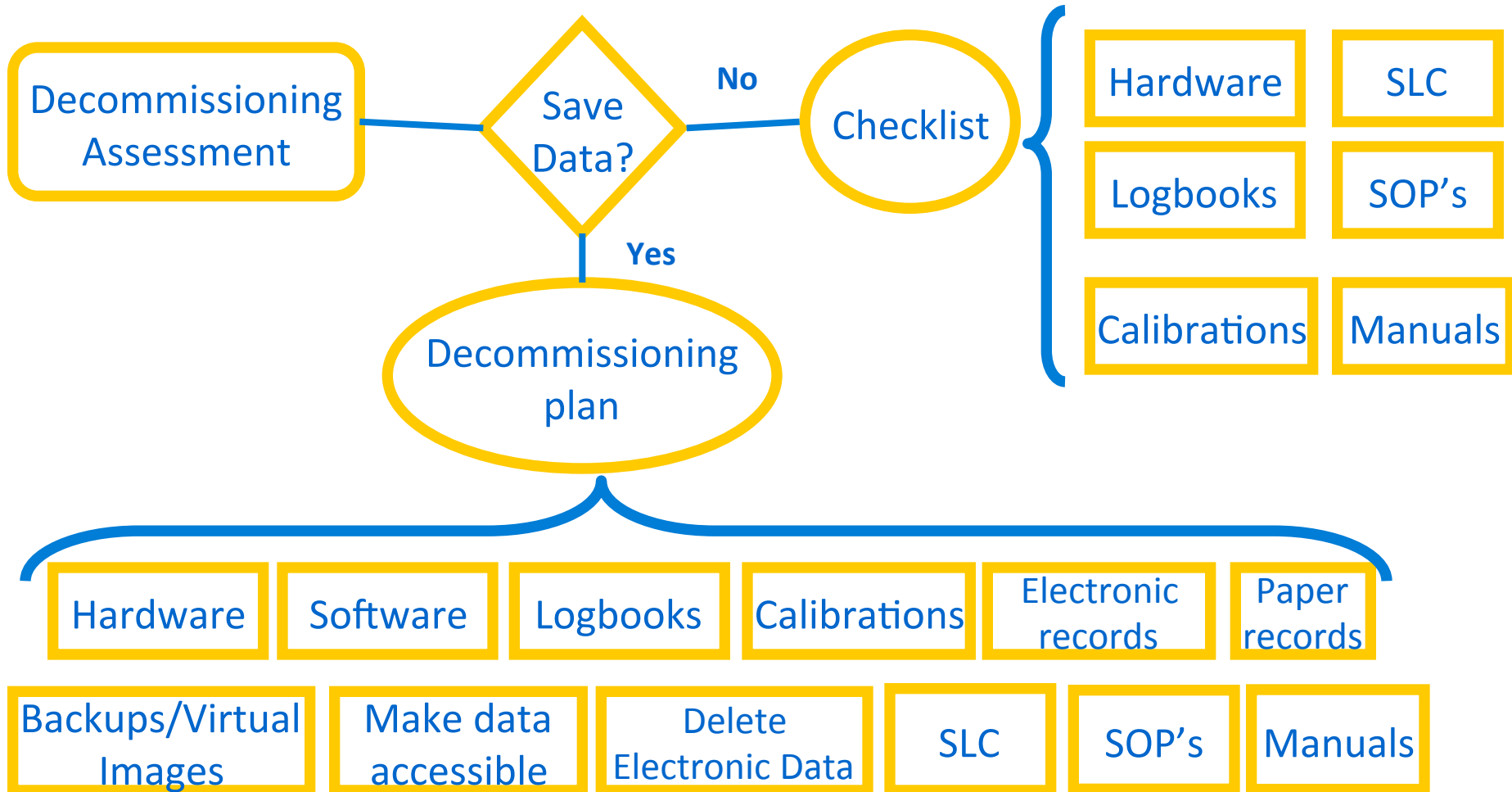


- 9567 Samples
- 2054 boxes of Retention Samples and 7 boxes of Stability Samples

Records Management: Summary

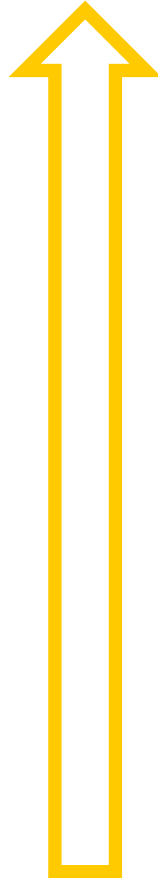
	Samples	Batch Records	SLC and Non GMP Documentation	Total
B i n d e r s	0	+ 2061	+ 6567	= 8628 ARCHIVED BINDERS
B o x e s	2061	+ 709	+ 2357	= 5127 ARCHIVED BOXES

Decommissioning of GMP Equipment and Systems



Decommissioning of GMP Equipment and Systems

**Stages for
Decommissioning
Equipment or
Systems**



Post-approval

Execution

Pre-approval

**Creating decommissioning
document and data treatment**

**Assessment, collection & reading
documentation of the equipment or
system.**

Decommissioning Documents

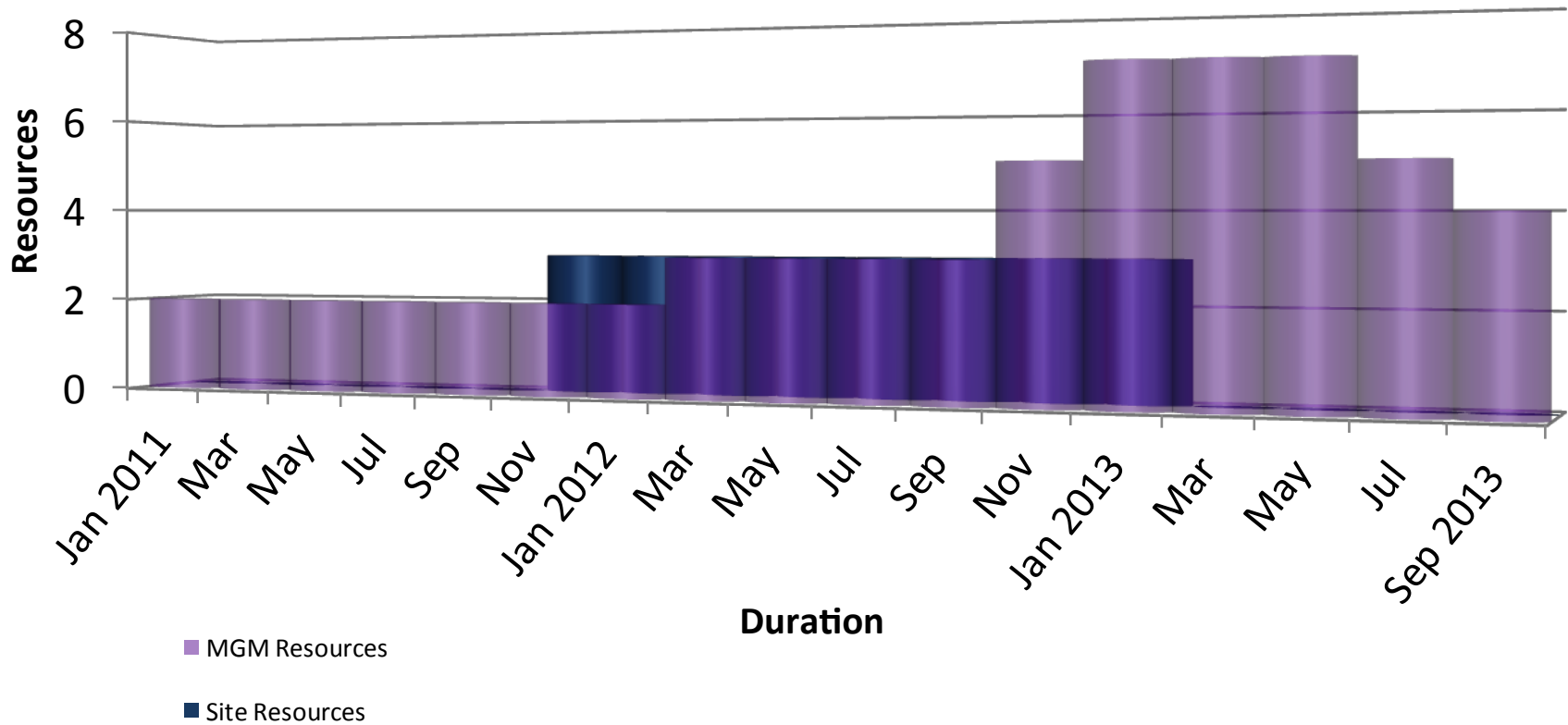
Equipment	Department	DPs	Images	CLs	Memos	
512	Quality	15	8	28	9	
	Manufacturing and Pakaging	2	1	20		
	Utilities	0	0	4		
	TOTAL	17	9	52	9	87

Project Resources Average/Duration Summary

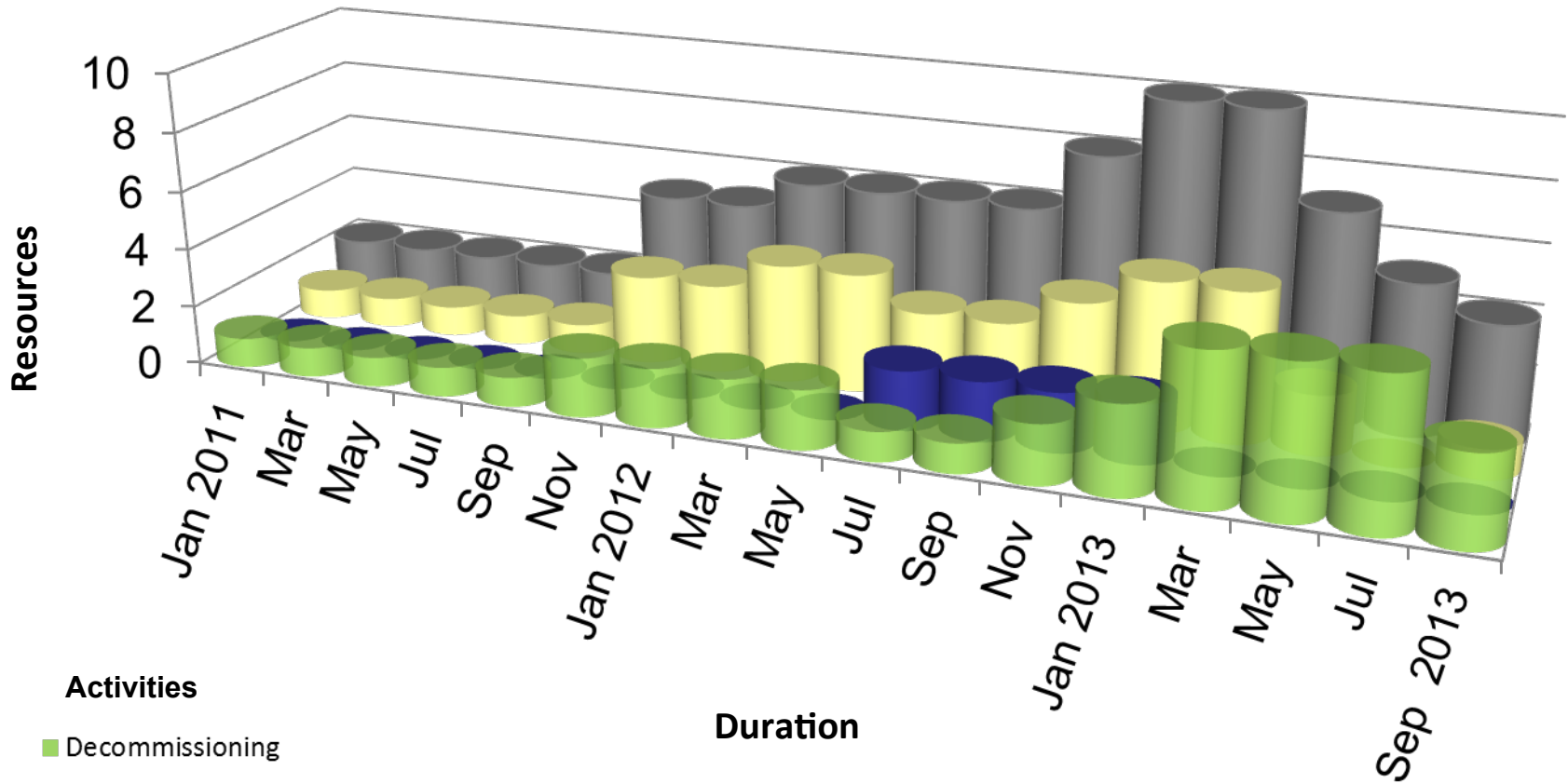
Resources (full time) and duration:



Resources / Duration



Resources /Activities



- Activities**
- Decommissioning
 - Samples
 - Records
 - Total Resources

Additional Support Activities

EMEA QUALITY OPERATIONS:

-Memo Quality Assurance

TSA:

- User's Manuals and EHST documentation copy: 942 manuals and 50 binders
- Batch Records for Consumer Complaints Investigation
- SLC/Non GMP documentation copied: 35 binders
- Training Records copied: 5 binders

Additional Support Activities

TSA:

- Calibrations and logbooks copied: all from July 2012
- Site Master File cleaned and given to buyer: 20 word documents
- SOPs cleaned and given to buyer: 396 word documents
- Records management support during Regulatory Inspection

AIFA