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Integrated Filling Line With Automatic Loading System for FD Product

Yekta Cakmak Yuce & Arda Inancli
Deva Holding Inc.
2014 PDA Europe Conference
24 June 2014, Istanbul

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AGENDA

- Introduction
- Layout & Classification
- Equipment Definitions
- Project Schedule
- Start-Up
- Manual & Automatic System Comparison
- Project Challenges
- New Technology & Challenges

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INTRODUCTION

Headquarter

ÇK-1

ÇK-2

Kartepe

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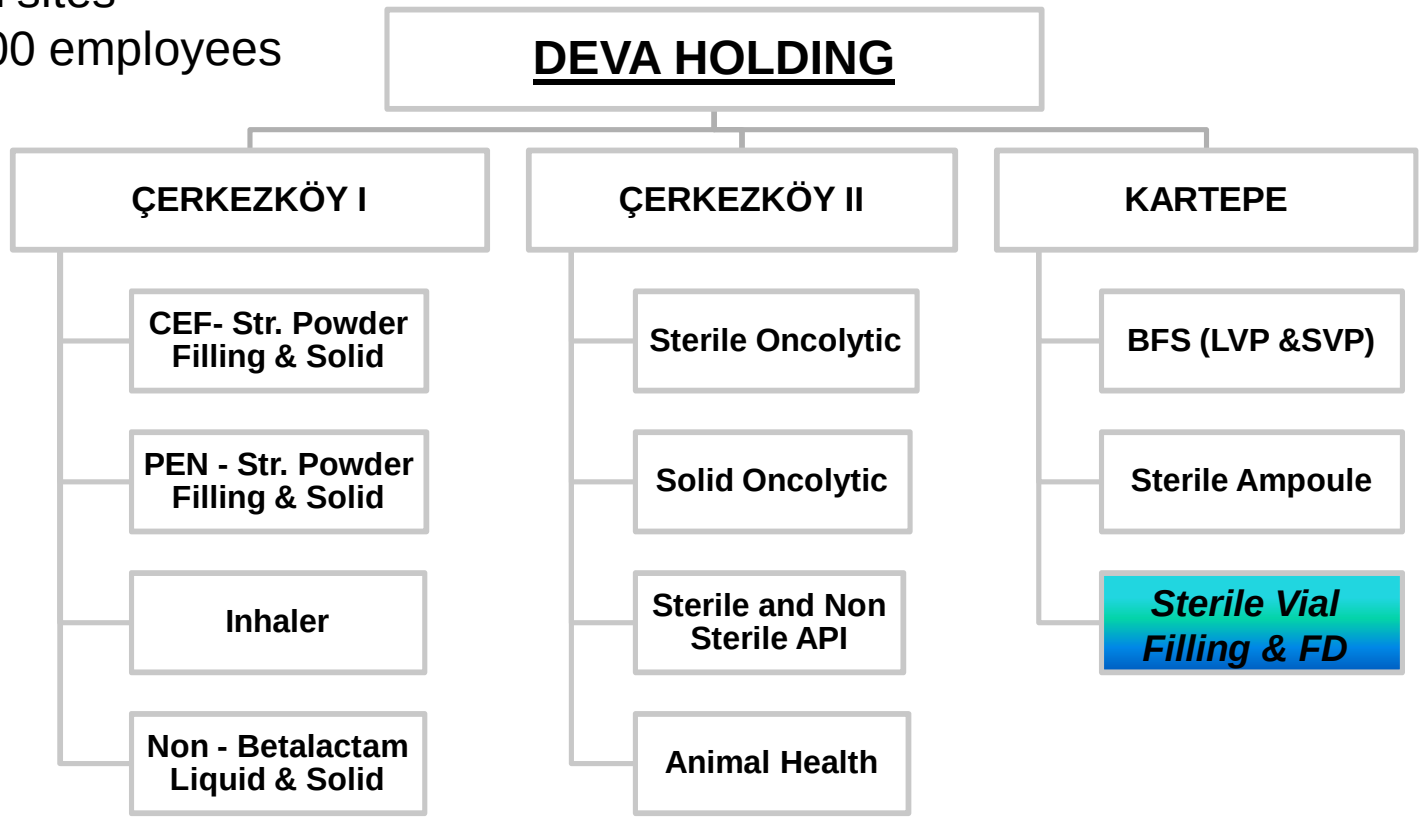
DEVA HOLDING INC.

- 3 production sites
- Approx. 2000 employees
- R&D center



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Å Deva Kartepe Site Sterile Production Lines

- ï 2 Ampoule Filling Lines
- ï 1 BFS SVP Filling Line
- ï 1 BFS LVP Filling Line
- ï ***1 Vial Filling & FD Line***

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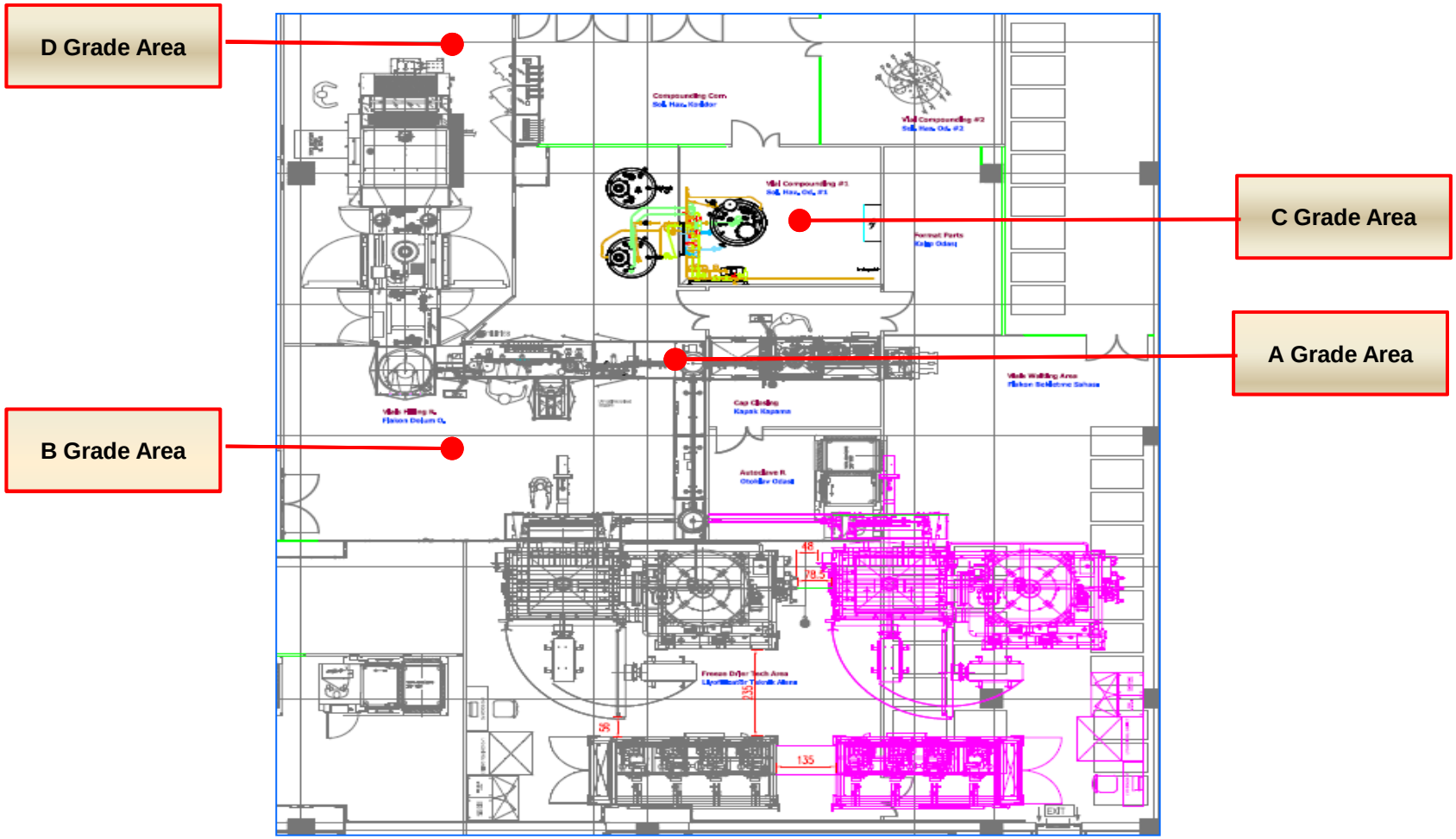
LAYOUT & CLASSIFICATION



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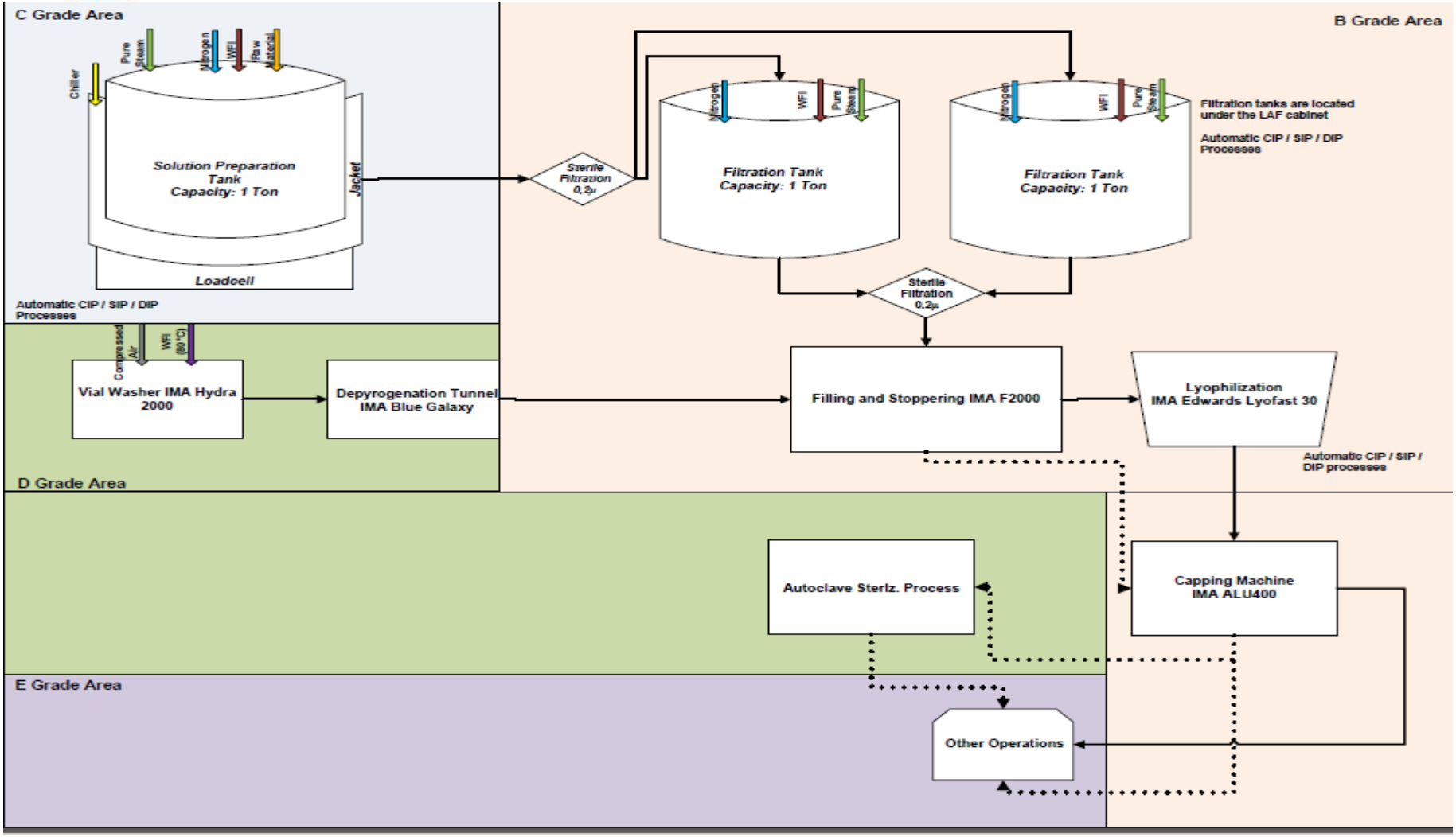

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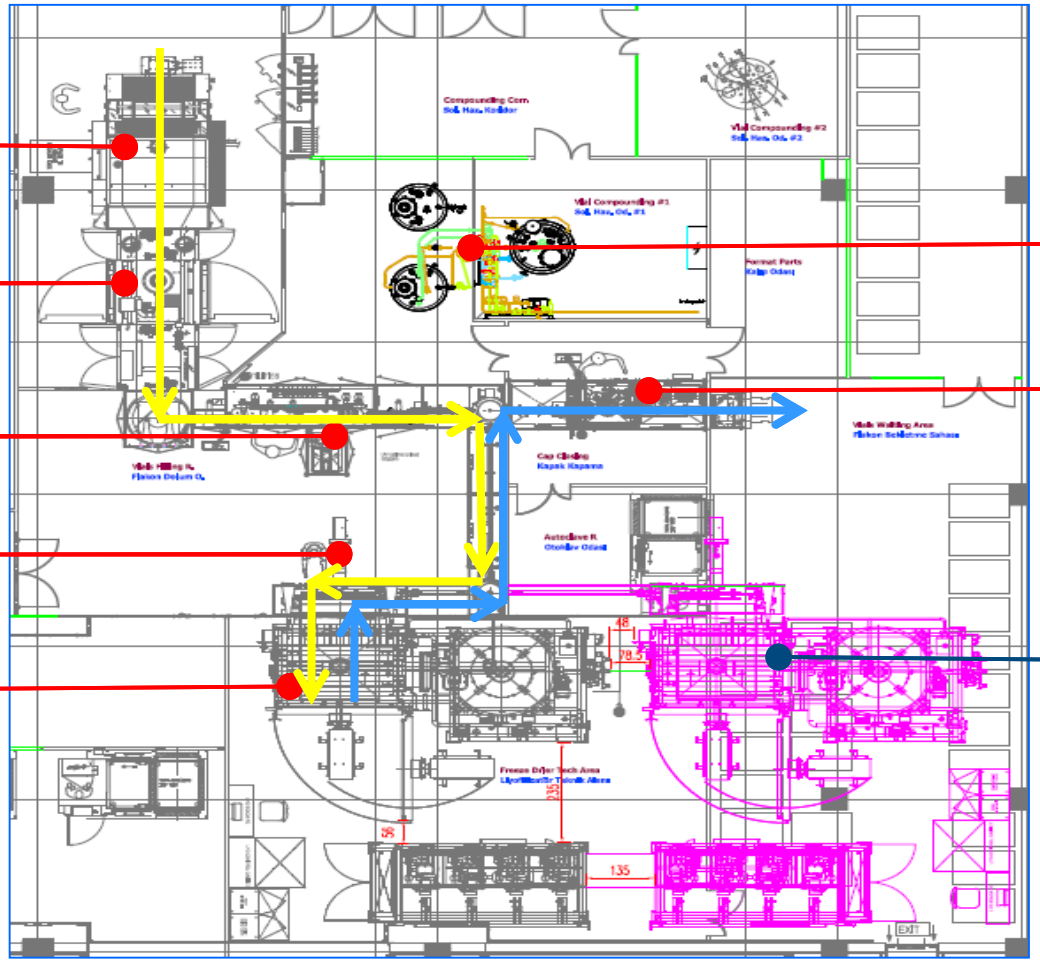

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Details of Integrated Filling Lineé

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Å Vial Washer

- ï Integrated with dep. tunnel
- ï WFI, compressed air and recirculation water
- ï Vial size; 2r to 250 ml

Å Depyrogenation Tunnel

- ï Integrated with vial filling and stoppering machine and vial washer
- ï 3 log reduction at depyrogenation cycle
- ï Automatic shutters and depyrogenation time delay
- ï Vertical air flow at infeed zone, heating zone and cooling zone

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Å Filling and Stoppering Machine

- Integrated with depyrogeantion tunnel, compact loading and unloading machine and capping machine
- Filling and stoppering 2r to 250 ml
- Operation at under the LAF
- Open RABs : Limited intervention & minimized
- operator intervention
- Airflow control under the LAF cabinet.
- N_2 blanketing
- Up to 8 ceramic rotary piston filling pumps
- Up to 8 rotary filling pumps
- Max speed 24.000 vial/h

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Å Compact Loading and Unloading Machine

- ï Integrated with filling and capping machine, freeze dryer and capping machine
- ï Operation at under the LAF
- ï Fully automatic loading and unloading operations
- ï Open RABs : Limited intervention & minimized operator intervention

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Freeze Dryer

- Integrated with CLU
- 13 shelfes 14 shelfes
- Total shelf area; 30m^2 40m^2
- CIP and SIP cycles
- Working range; -55 ^{0}C to 80 ^{0}C
- Ultimate system vacuum ; 0,01 mbar

Capping Machine

- Integrated with vial filling and stoppering machine and CLU

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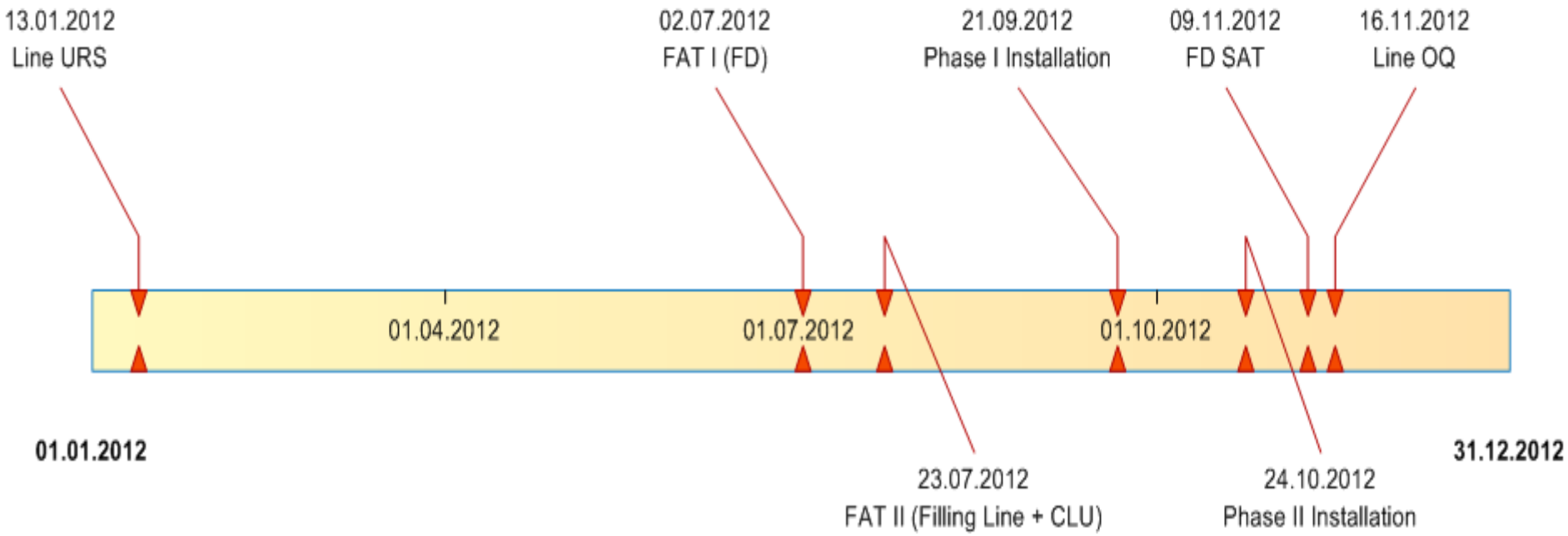
PROJECT SCHEDULE



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- **FATs**
- Approx. 3 week for all line
- Vial Washer and Dep. Tunnel ï Bologna ï with 4 staff
- Filling Machine, Cap Closing Machine and CLU ï Florence ï with 4 staff
- Freeze Dryer ï Beijing ï with 5 staff

SATs

- Approx. 2 week for all line
- Performance runs for each machine
- Heat penetration and air quality tests for tunnel

IQ and OQ

- 4 week for all line
- all function and alarms tested

PQ

- 1 week
- Performance runs ï matrixe of size (except depyrogenation tunnel)

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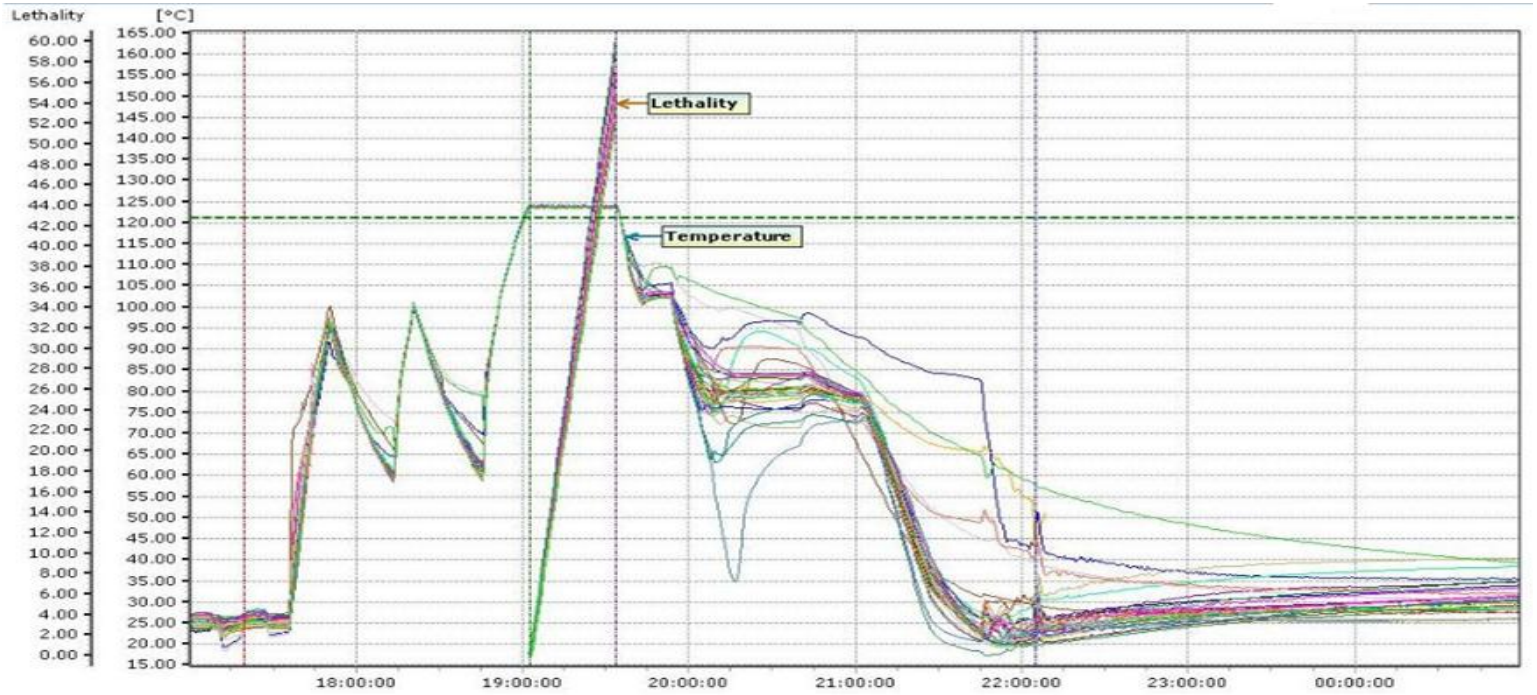
Critical points for contamination

- Air flow directions
- SIP validation



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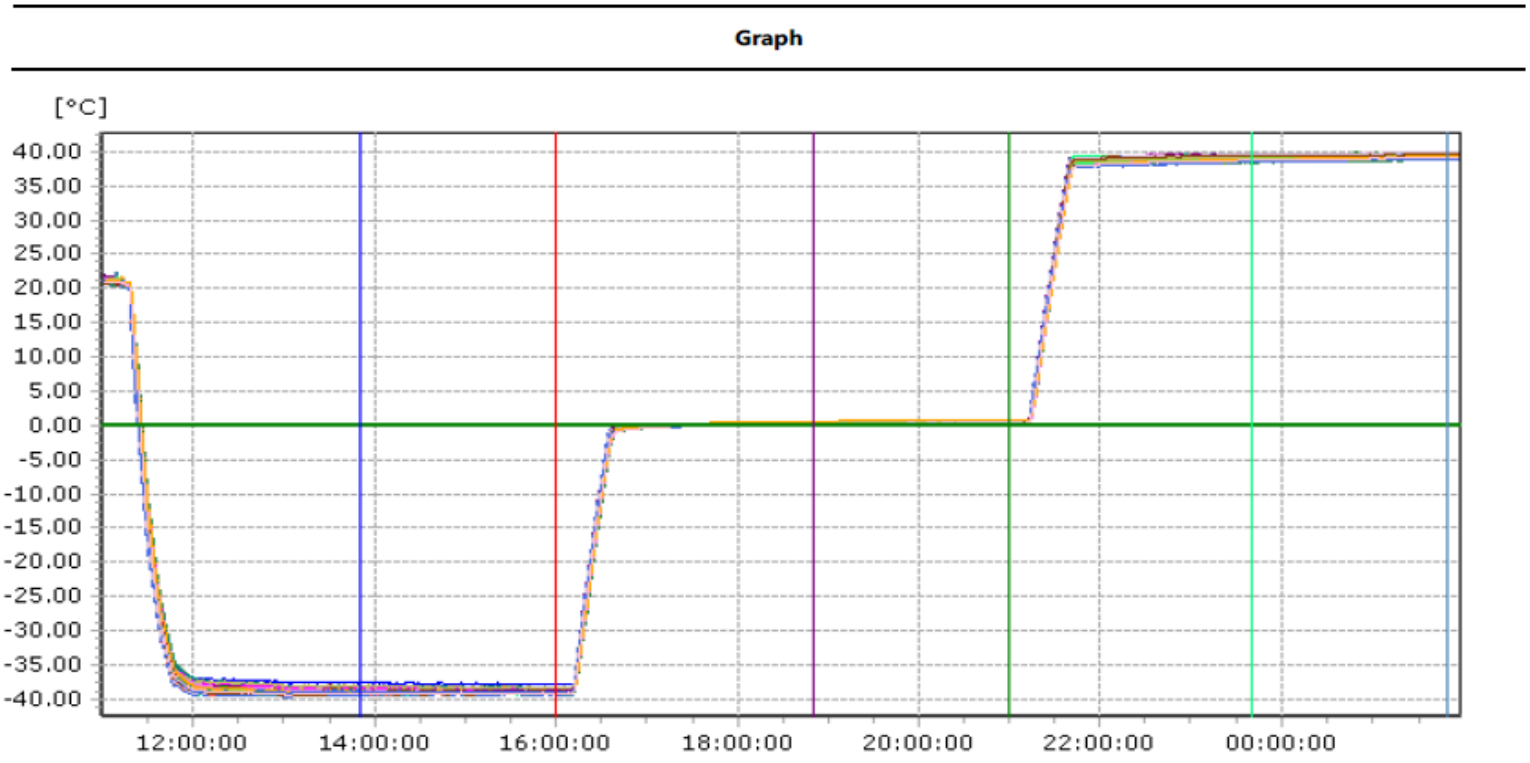
Critical point for product quality

ï Shelf mapping for FD



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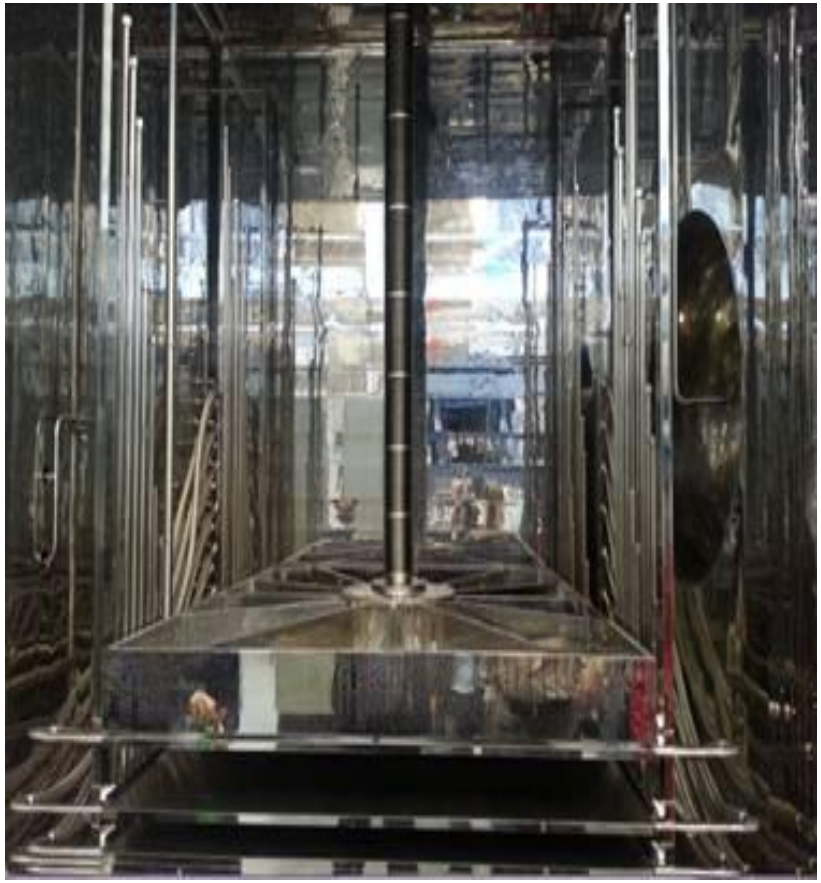
CIP Coverage test (with Riboflavine)



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PROJECT CHALLENGES

- Utilities (building reinforcement, Water system, HVAC etcé)
- Time schedule - short time
- Other on-going projects
- New technology : improving new approach
- Handling of small formats

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NEW TECHNOLOGY & CHALLENGES

- Flexibility
  - From 2 ml to 250 ml
  - Processing 2 different product at the same time (lyo./ non-lyo.)
- Fully Automated - Controlled
- Less Intervention
- Less Contamination
- Less Manpower
- High Capacity

- Difficult to manage
- More and more training
- More and more qualification activities

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*We would like to thanks for DEVA Holding, IMA Life Science & LIKKON Coorporation**é***

*Thanks for your attention**é***