



# Strategy for digitalization in GMP environment: The Ferrer Group's journey

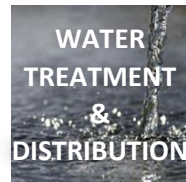
Fernando Quintero  
Marc Olivé Torralba

# Agenda

- Industry 4.0 project
- Project Challenges
- Results
- Future vision

# AG Solution in a nutshell

 AG Solution  
**builds intelligent  
solutions** for  
the **process industry**



 We offer customers  
a broad experience and  
high quality in building

- **Automation Systems**
- **Process Control**
- **Data Management**
- **MES/MOM solutions**
- **Operational Intelligence**
- **Industry 4.0 consultancy**

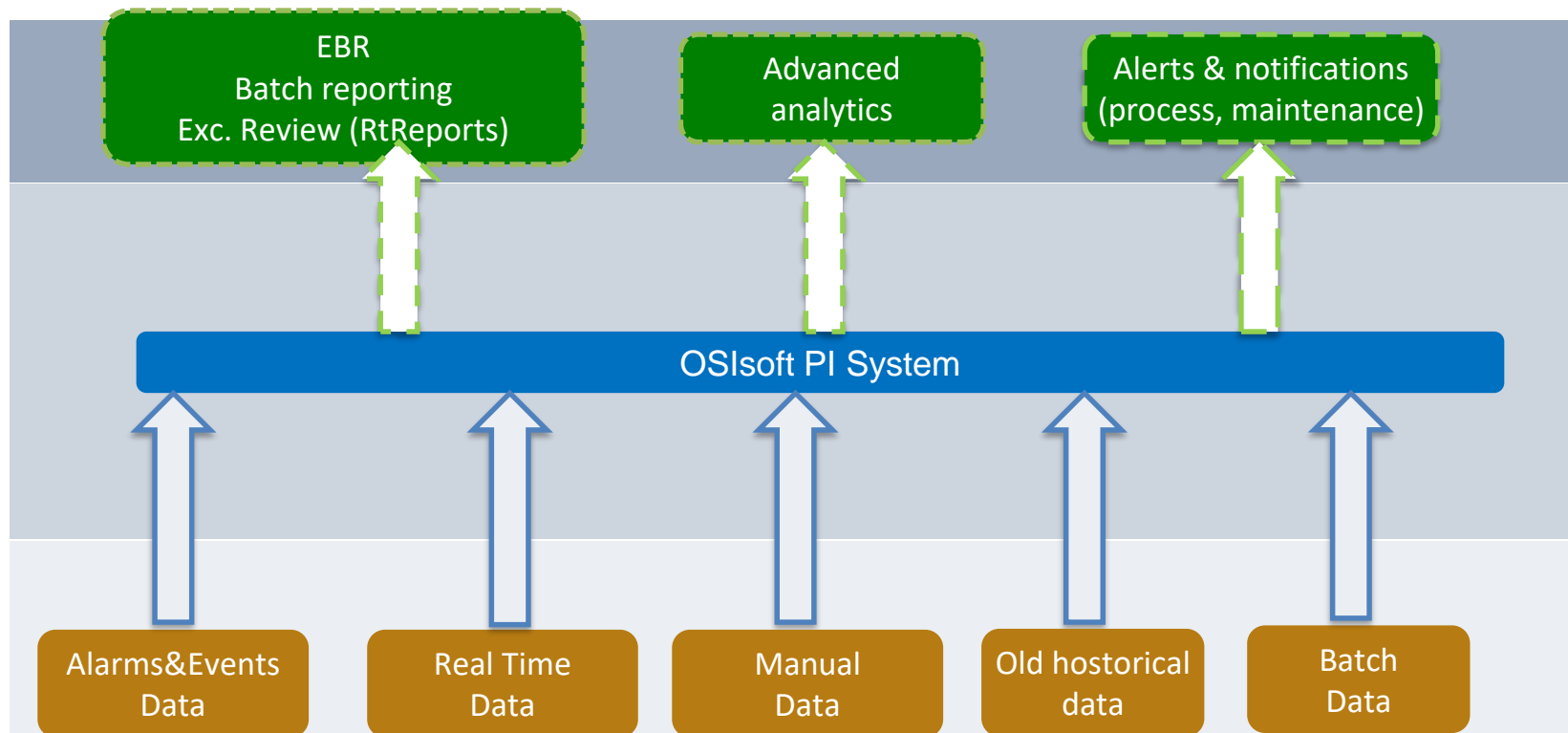
# Initial Business Case

Ferrer Group wanted to migrate their Historian to a **modern, stable** Data Infrastructure and fully compliant with **regulatory norms**.



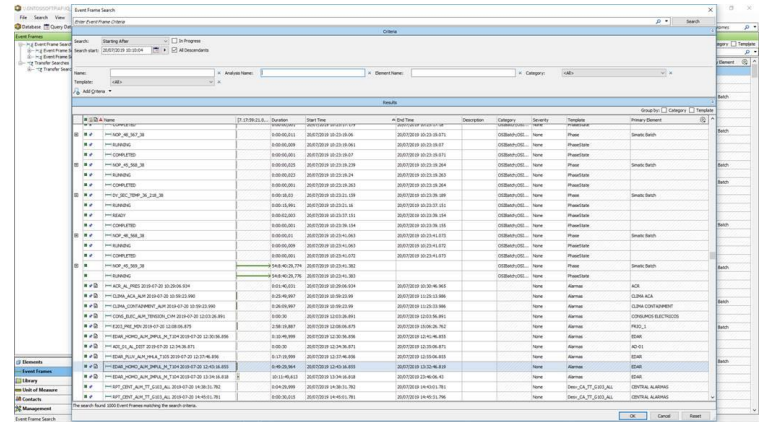
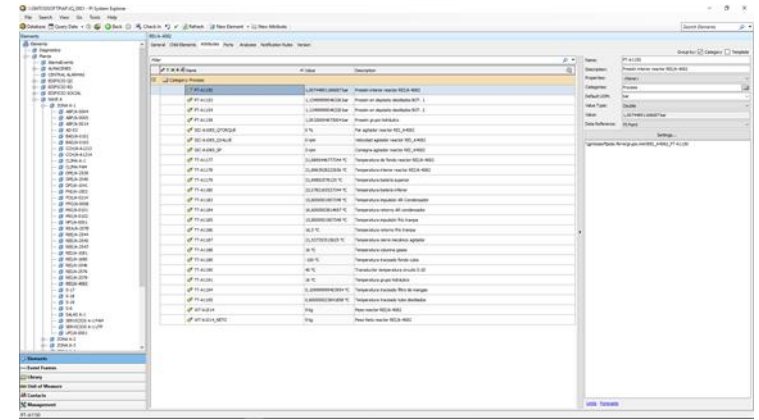
- ✓ More Stability
- ✓ Capability to integrate several Data Sources
- ✓ Improve procedures by eliminating paper-based actions

# OSIsoft PI Data Integration



# Creation of Plant Model

- ✓ AF model for asset supervision → PI Notifications
- ✓ Integration with Batch System, S88 based model with all recipe parameters In Event Frames → EBR creation



# Quality improvements

## Using RTReports:

### Introduction of Review by exception

Full list of parameter deviations (with ST, ET)

Focus on deviations→

Time saving Quality procedures

### EBR Creation

Batch reports with Recipe parameters



Receta		
Nombre		Versión
Cliticolina Sal Monosódica		V4.95
Producto		
Nombre		Cantidad Actual
Cliticolina Sal Monosódica		1
Orden		
Orden Category		Order Name
A-6		6000094- A19046A(31951)
Duración		
Inicio	Duración	Fin
11-Feb-19 17:33:33.327	8 days 9 hours 57 minutes 42,352 seconds	20-Feb-19 03:31:15.680

Tabla Desviaciones

Criterio Aceptación: Caudal Elución <= 110 l/h

Tipo	Inicio	Final	Duración
Sin Desv.	11-Feb-19 18:24:47	12-Feb-19 00:16:04	5 hours 51 minutes 16,819 seconds

Tabla Desviaciones

Criterio Aceptación: Temperatura Masa <= 40.5 oC

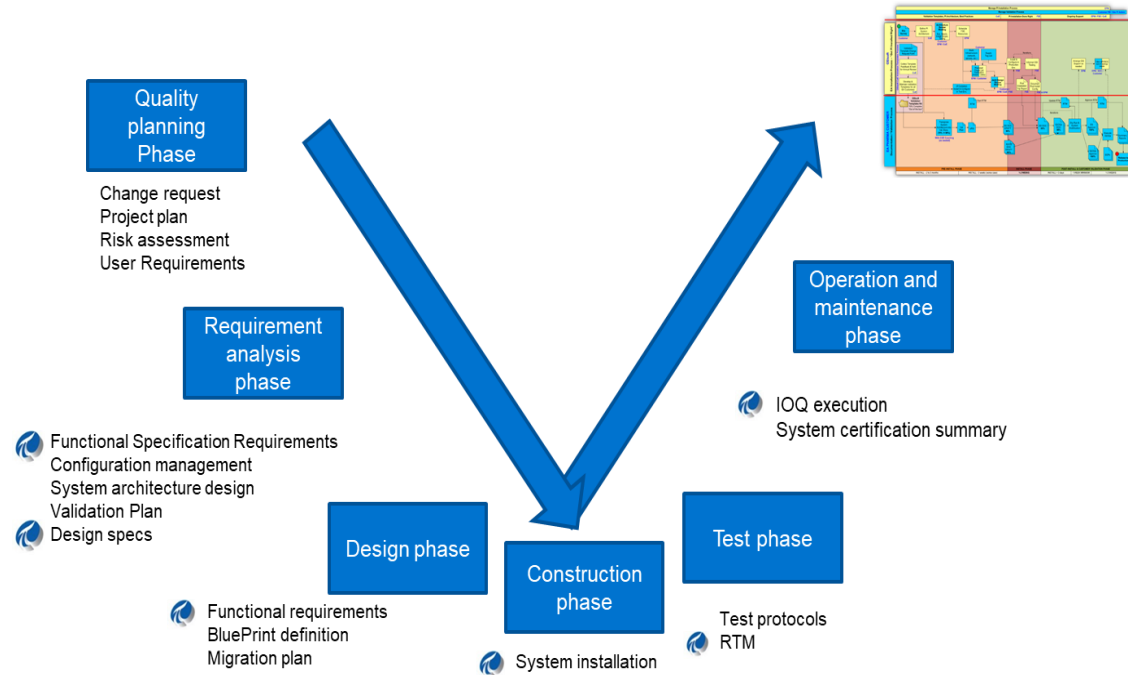
Tipo	Inicio	Final	Duración
Sin Desv.	11-Feb-19 18:24:47	12-Feb-19 00:16:04	5 hours 51 minutes 16,819 seconds

# Validation process

- Infrastructure Qualification
- Templates
- Training and support

## Advantages:

- Time saving
- Optimal validation level





# Project challenges

## GMP environment

Regulated  
environment  
Compliance  
21 CFR part 11  
GAMP V

## Blue Ocean

Industry 4.0  
projects are still  
unknown in  
capabilities and  
benefits

## User adoption

- Introduction to a new system
- Understanding capabilities
- Resistance to change reduction
- Change in working conducts

## Joint effort

- IT
- QA
- Production
- Engineering
- Continuous improvement
- Management and business

**Training and coaching!**

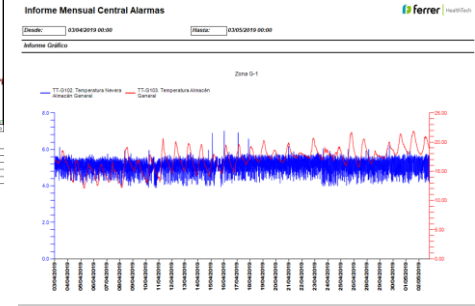
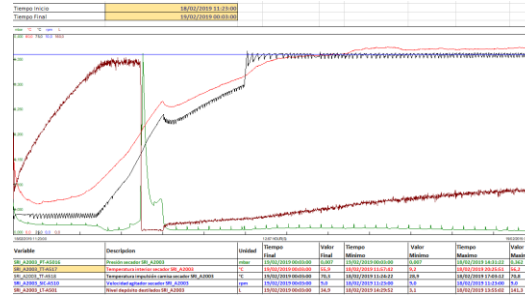
# Final Project results

## Initial objectives accomplished:

Installation of Data Infrastructure

Paper reduction

Data integrity



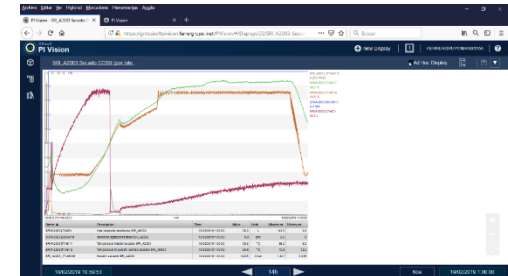
## + Improvements in:

Automation and operations improvement (alarm management, process control definition)

Quality system (review by exception), automation of quality supervision

Access to operational information

Reduction in operational mistakes



# Future vision

## Explore new possibilities

- Alarm management (ISA 18.2)
- Introduction of new KPI's (production, quality, performance)
- Group level expansion & roll-out



# Interquim road to continuous process awareness



## CHALLENGES

- Paper reduction
- Data integrity
- Improvement of quality and production procedures
- User adoption

## SOLUTION

- Installation of Data infrastructure
- Integration with all operational data sources
- Creation of Data Context with PI AF
- System Validation (21 CFR part 11, GAMP V)

## BENEFITS

- Improvement in:
- Automation and operations improvement
  - Quality system (review by exception), Access to operational information
  - Reduction of operational mistakes



The PI System allowed Interquim to digitalize their production site by implementing EBR, all this by being fully compliant with regulatory norms



# Thank You

# Fernando Quintero

Regional Automation Manager | AG Solution

[Fernando.Quintero@agsolutiongroup.com](mailto:Fernando.Quintero@agsolutiongroup.com)

# Marc Olivé Torralba

Technical leader MES/MOM | AG Solution

[Marc.torralba@agsolutiongroup.com](mailto:Marc.torralba@agsolutiongroup.com)

# Questions?

Please wait for  
the **microphone**

State your  
**name & company**



# Please remember to...

## Complete Survey!

Navigate to this session in  
mobile agenda for survey

