GxP Compliant Alarm Handling with Event Frames and AF

Presented by

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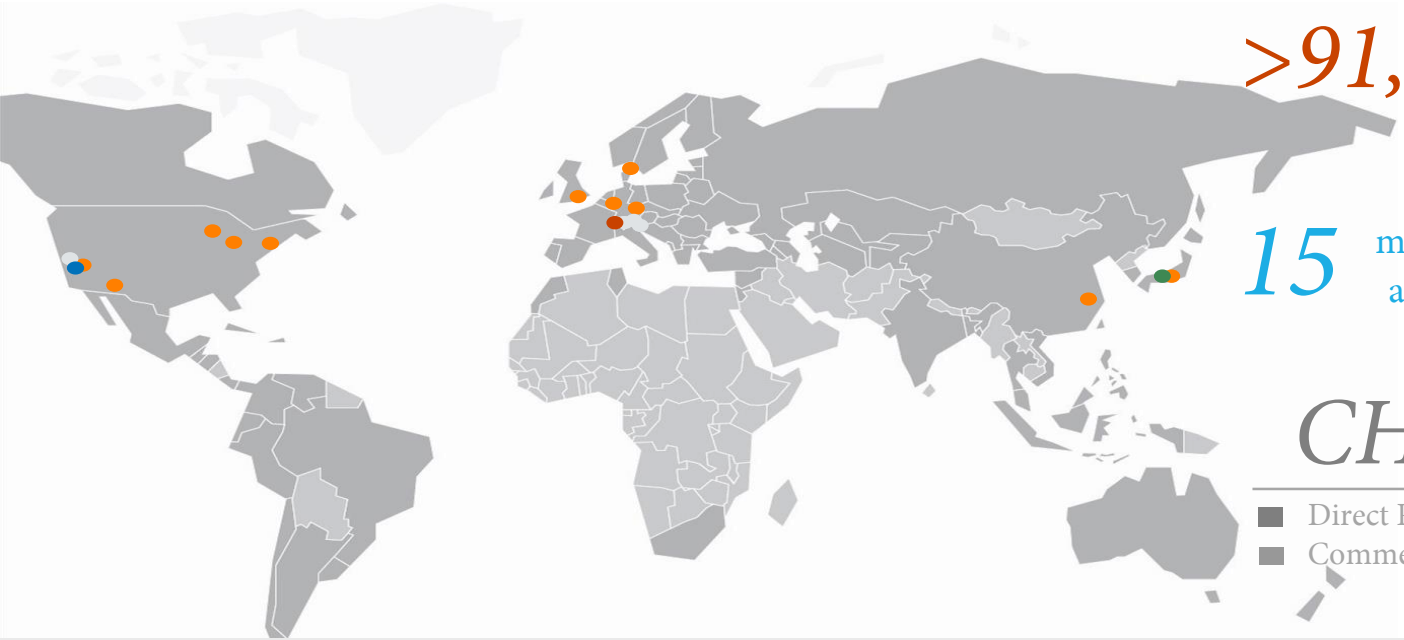
Roche: A Global Pioneer in Pharmaceuticals and Diagnostics



>91,700 employees worldwide

15 major R&D sites in pharma and diagnostics worldwide

CHF 48.1 billion sales

- Direct Roche commercial presence
- Commercial distributors

- Roche Group Headquarters in Basel, Switzerland
- R&D sites in Pharma and Diagnostics
- Genentech, R&D and commercial operations US
- Chugai, R&D and commercial operations Japan

RIPIN

The RIPIN (**R**oche **I**nterface for **PI** Eve**n**t Frames) application replaced the Alarm Viewer interface by a GxP compliant interface for PI Event Frames, using standardized Event Frame templates with attributes and an AF Server as a meta database. It provides a link to a Coresight adhoc display for every alarm.

The newly created custom GUI that allows users to acknowledge and annotate alarms/events is web-based and can also be used on mobile devices

Drivers

Reason for the project

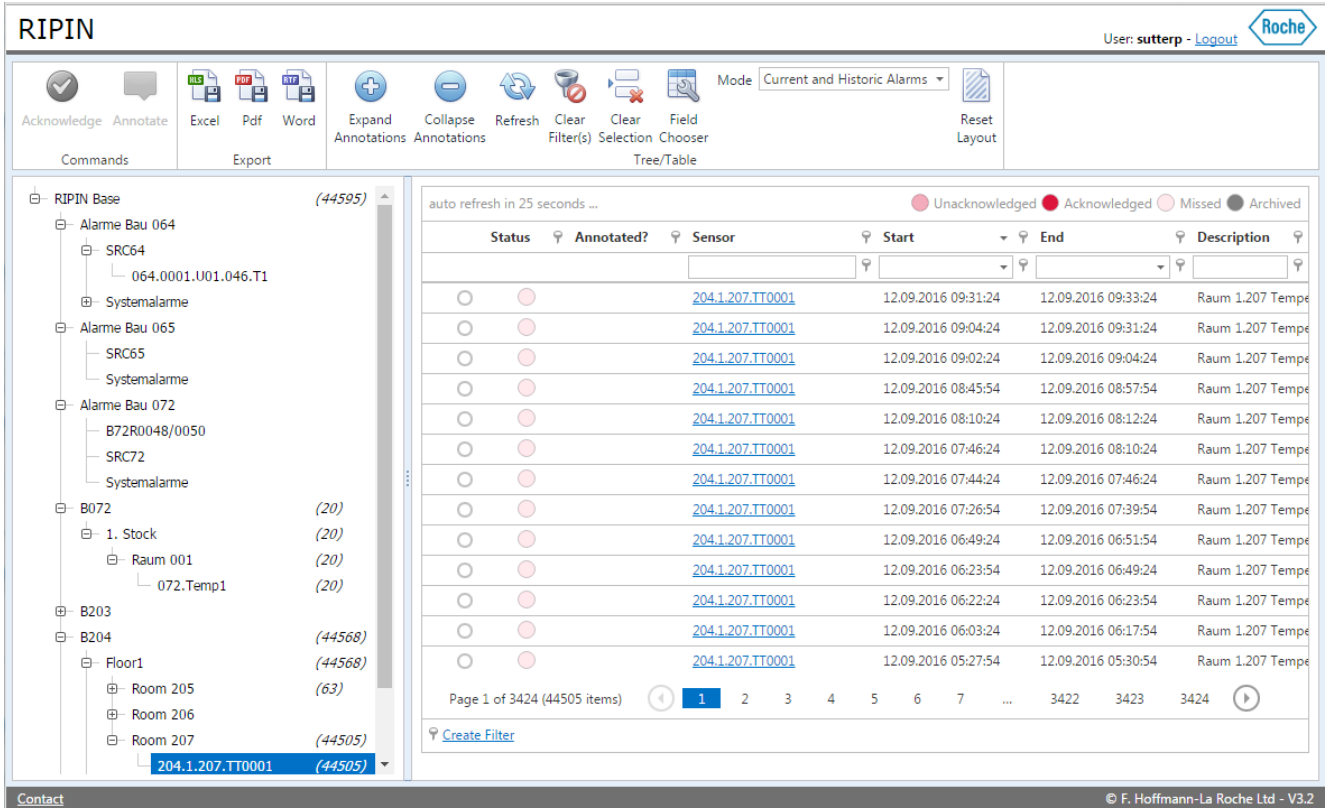
- Findings during internal audit
- Acknowledgement of alarms did not store who acknowledged it
- No possibility to configure the workflow (Alarm could be acknowledged without annotations)

Measurable value

- Reducing risk of release delay or lost batches due to alarm handling problems
- Right to target

Design: How does RIPIN use the PI System infrastructure

RIPIN – What the End User Gets



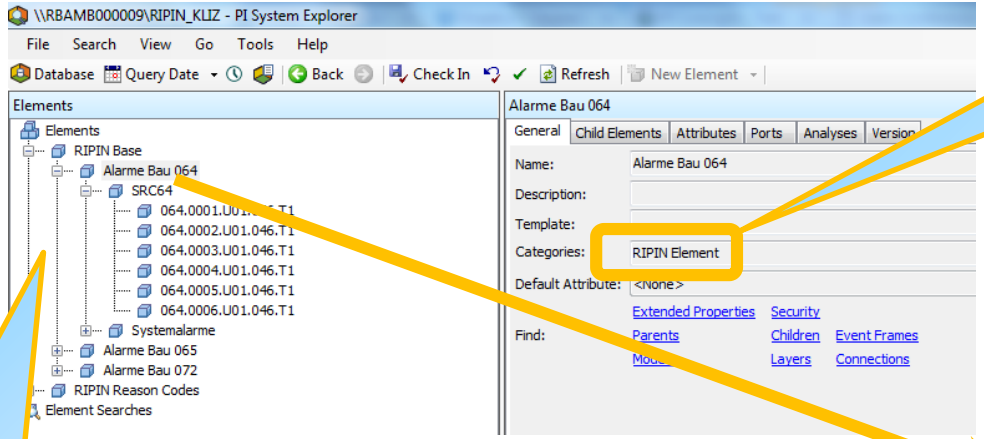
RIPIN Design - Distribution of Tasks

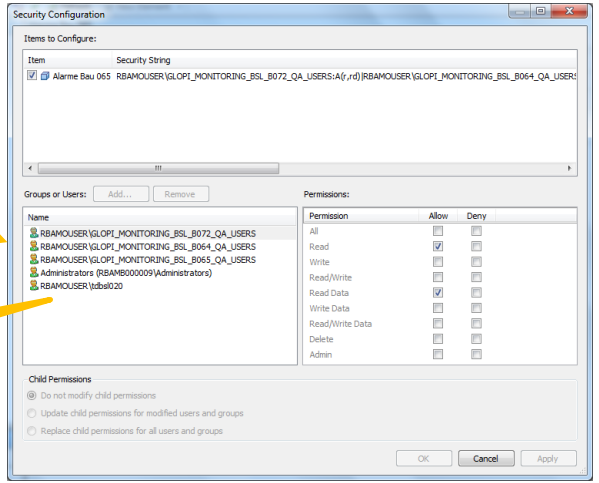
- Main Idea: use existing PI System infrastructure where possible
- Create small, independent units
- Use templates, categories
- Extensibility, use standard PI System tools for data access
- Backwards compatibility

RIPIN Design – Use Existing PI System Infrastructure

- AF tree for alarm hierarchy
- Visibility by Categories and AF security
- Templates for Sensors
- Alarms modelled as event frames based on EF template
- Attributes to store our information

RIPIN Design – Alarm Hierarchy in AF





Categories to specify general visibility

Alarm Hierarchy

AF Security for individual Visibility

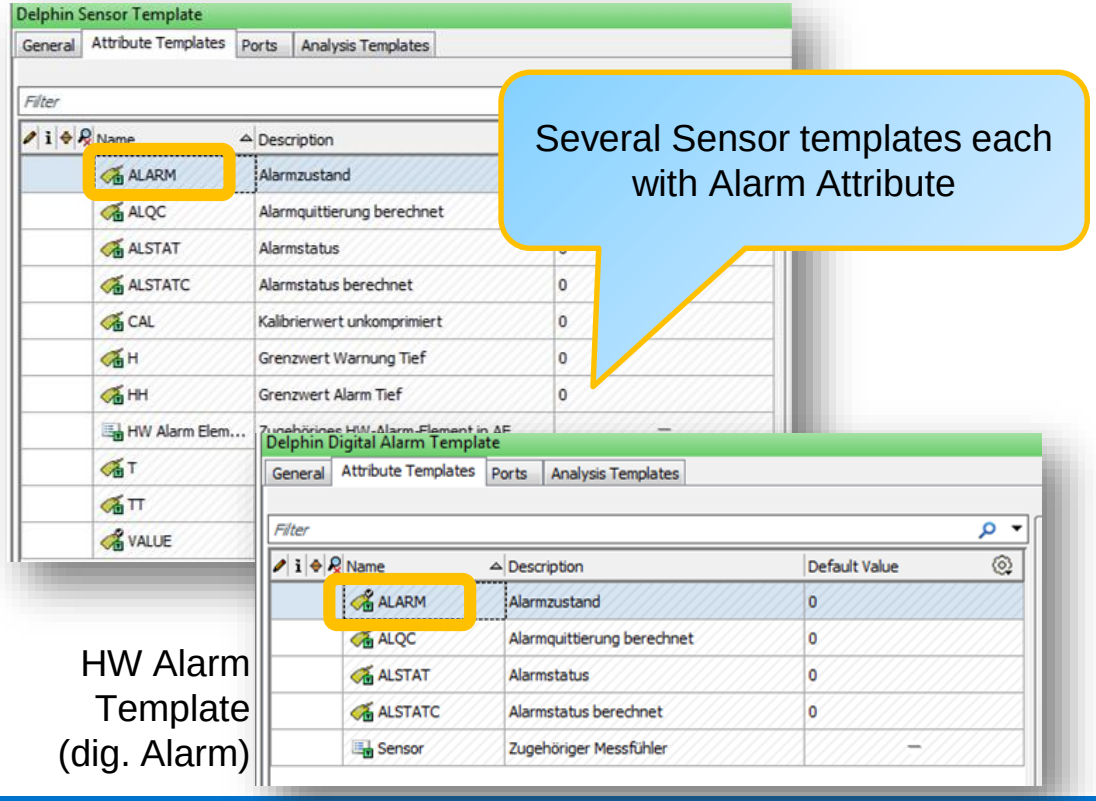
RIPIN Design – AF Templates

- Templates for
  - Sensors that can create Alarms (Element Templates)
  - Alarms (Event Frame Template)
- Alarm Types
  - Analog alarms (e.g. Temperature crossing high limit)
  - Digital alarms (e.g. Hardware alarm, Sensor problem)

➔different element templates (same category, same EF template)

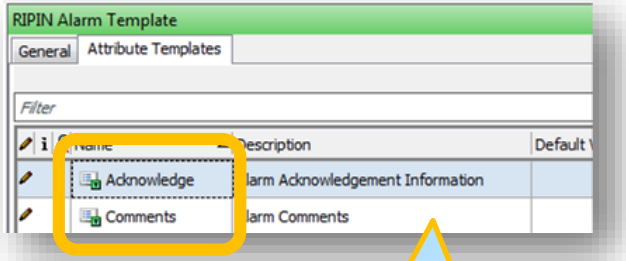
RIPIN Design – Templates, Attributes

Sensor Template (Analog Alarm)



HW Alarm Template (dig. Alarm)

Event Frame Template

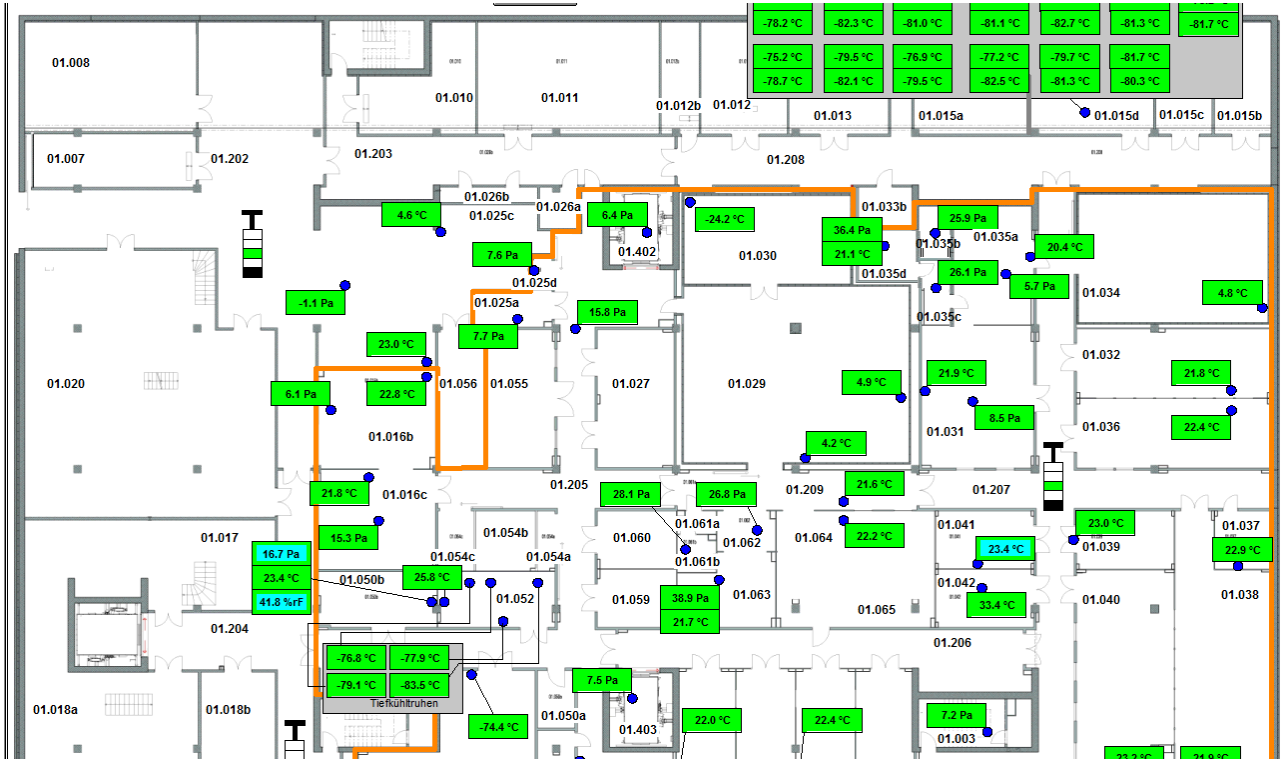


Event Frame Template With String Attributes for Ack and Comment

RIPIN Design – Event Frames, Creation

- Events are created using the EFGen Interface
  - –Create EFGEN configuration using powershell script based on list of sensors
- Event generation is not a function of RIPIN, can be replaced e.g. with an EF analysis directly in AF
- Event Attributes contain all information relating to alarm treatment (comments, ack information)

RIPIN Design – Backwards Compatibility



Alarms displayed in ProcessBook

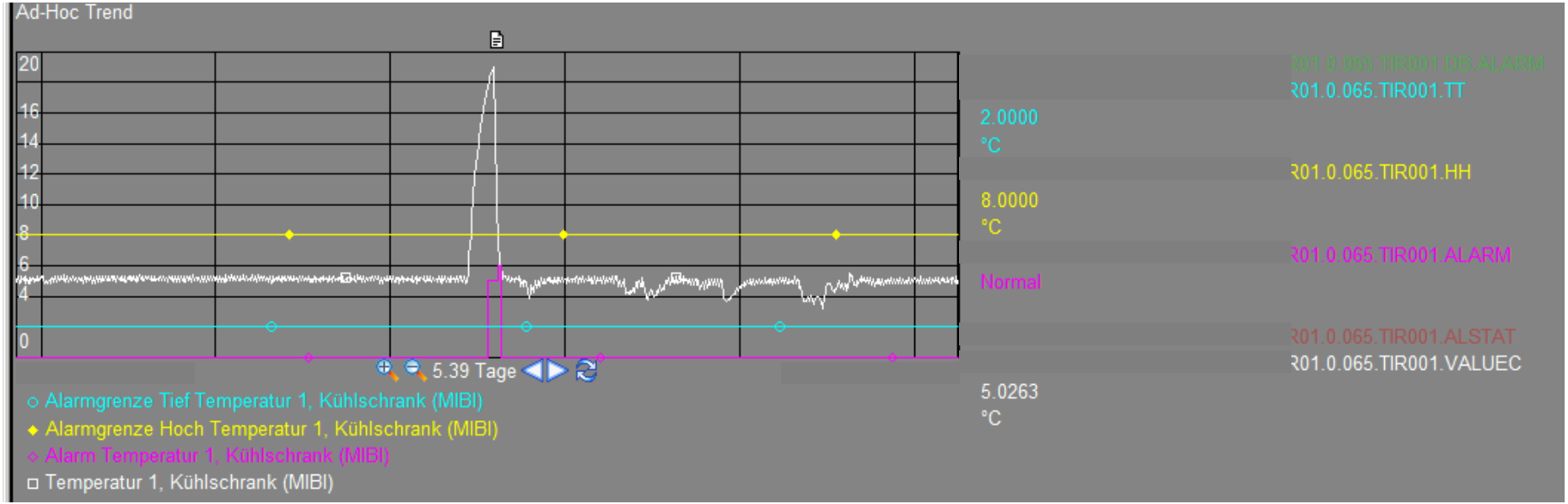
Existing Displays must be usable with RIPIN

Background color codes:

- Green: Normal
- Red blinking: active Alarm
- Red steady: ackn. Alarm
- Pale red blinking: missed
- Blue: inactive

RIPIN Design – Backwards Compatibility

- Alarm states
- Annotations



RIPIN Design – Extensibility

- All RIPIN data is in the PI System, therefore it is accessible using all the normal client tools (DataLink, PI OLEDB Enterprise etc.)
- Usage Ideas:
  - –create alarm trending statistics using a cube with SQL Server Analysis services
  - –Find sensors that trigger alarms most often/stay in alarm for the longest times
  - –...

RIPIN User Interface:

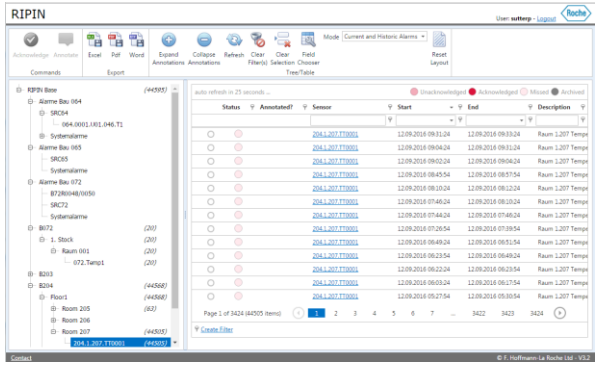
RIPIN

DEMO

RIPIN – Summary

COMPANY and GOAL

Roche, a global Company, a pioneer in healthcare needs a GxP compliant alarm handling



CHALLENGE

GxP requirements

Internal audit findings

- Force users to comment every alarm before acknowledge
- System must store who acknowledged and commented the alarm

SOLUTION

RIPIN
A Software to manage alarms in a GxP compliant way

- Based on existing OSIsoft tools (AF, Event Frames, Coresight)
- Simple web based solution
- Backwards compatible to PI AlarmView

RESULTS

Dramatically reduced the risk of release delay or lost batches due to alarm handling problems

- Fully aligned to GxP requirements
  ➔ Eliminate QA findings
- Solution follows internal IT standards
  ➔ easy to install and maintain

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Questions

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State your **name & company**

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Complete the Online Survey for this session

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감사합니다

谢谢

Danke

Gracias

Merci

Thank You

ありがとう

Спасибо

Obrigado