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GxP Compliant Alarm Handling with Event Frames and AF

Presented by

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Philipp Sutter**

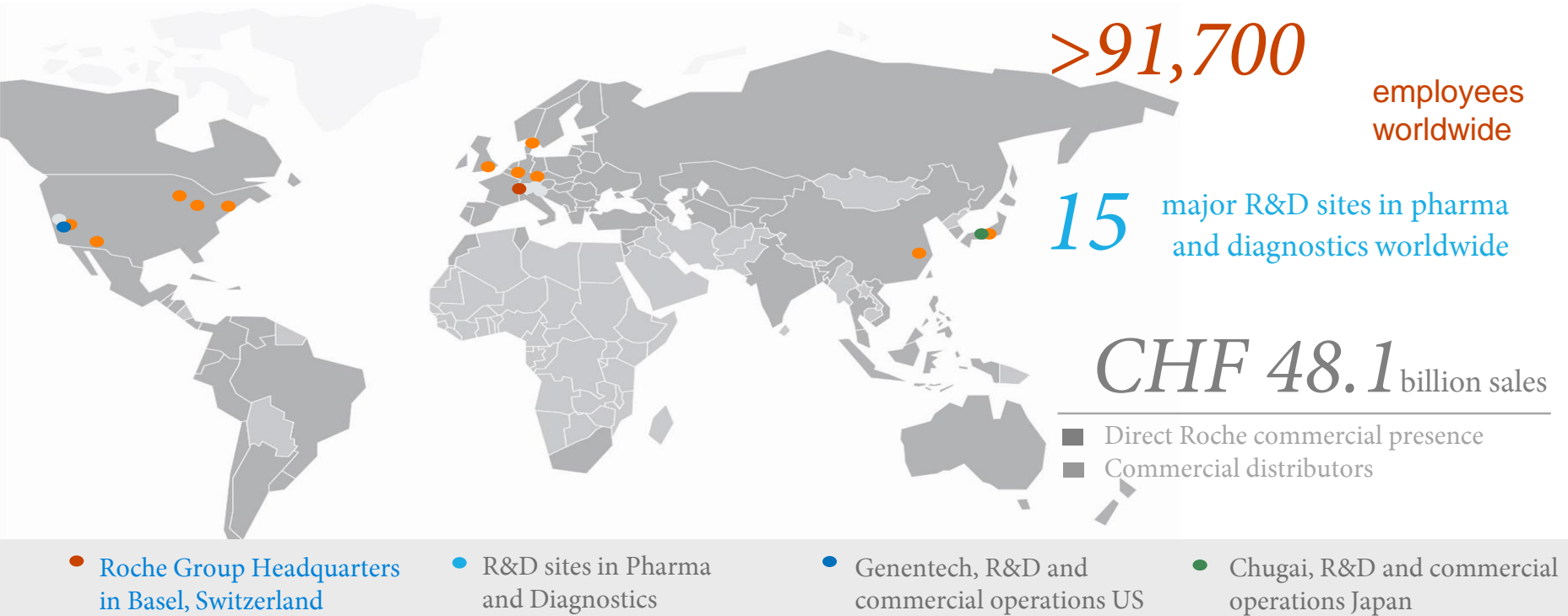


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Roche: A Global Pioneer in Pharmaceuticals and Diagnostics



RIPIN

The [RIPIN](#) (**R**oche **I**nterface for **PI** **E**vent **F**rames) 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 User: sutterp - Logout 

Commands: Acknowledge Annotate | Export: Excel Pdf Word | Annotations: Expand Annotations Collapse Annotations Refresh Clear Filter(s) Clear Selection Field | Mode: Current and Historic Alarms | Reset Layout

RIPIN Base (44595)

- Alarmer Bau 064 (44595)
 - SRC64
 - 064.0001.U01.046.T1
 - Systemalarmer
- Alarmer Bau 065
 - SRC65
 - Systemalarmer
- Alarmer Bau 072
 - B72R0048/0050
 - SRC72
 - Systemalarmer
- B072 (20)
 - 1. Stock (20)
 - Raum 001 (20)
 - 072.Temp1 (20)
- B203
- B204 (44568)
 - Floor1 (44568)
 - Room 205 (63)
 - Room 206
 - Room 207 (44505)
 - 204.1.207.TT0001 (44505)

auto refresh in 25 seconds ... ● Unacknowledged ● Acknowledged ● Missed ● Archived

Status	Annotated?	Sensor	Start	End	Description
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 09:31:24	12.09.2016 09:33:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 09:04:24	12.09.2016 09:31:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 09:02:24	12.09.2016 09:04:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 08:45:54	12.09.2016 08:57:54	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 08:10:24	12.09.2016 08:12:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 07:46:24	12.09.2016 08:10:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 07:44:24	12.09.2016 07:46:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 07:26:54	12.09.2016 07:39:54	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 06:49:24	12.09.2016 06:51:54	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 06:23:54	12.09.2016 06:49:24	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 06:22:24	12.09.2016 06:23:54	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 06:03:24	12.09.2016 06:17:54	Raum 1.207 Tempe
<input type="radio"/>	<input type="radio"/>	204.1.207.TT0001	12.09.2016 05:27:54	12.09.2016 05:30:54	Raum 1.207 Tempe

Page 1 of 3424 (44505 items) 1 2 3 4 5 6 7 ... 3422 3423 3424

[Create Filter](#)

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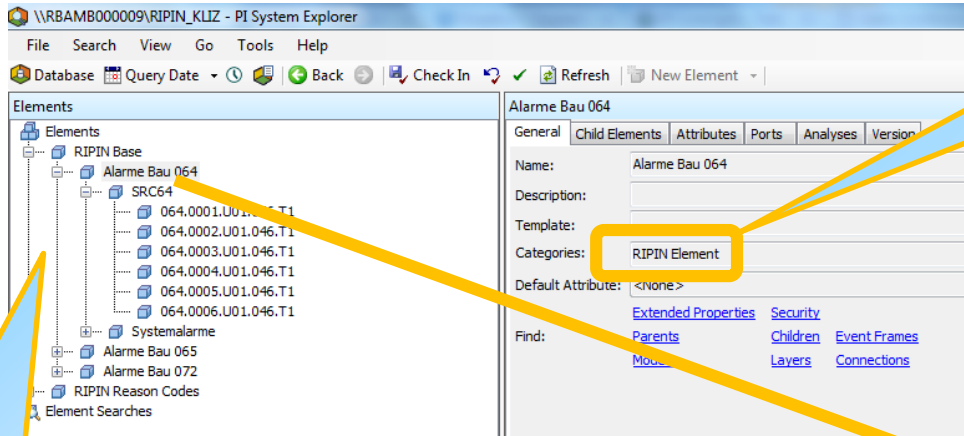
RIPIN Design - Distribution of Tasks

- 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

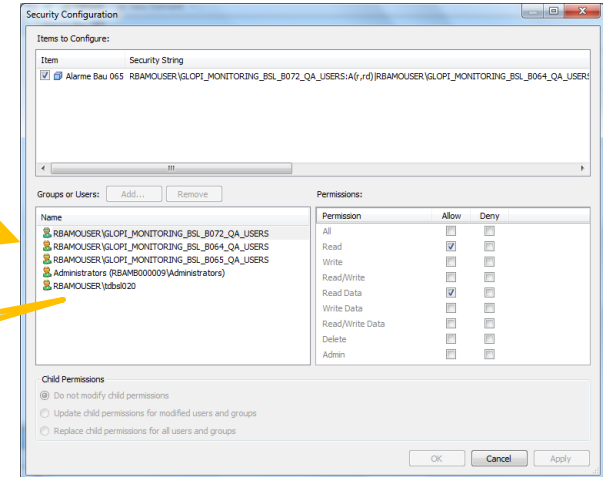
RIPIN Design – Alarm Hierarchy in AF



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)

Delphin Sensor Template

General Attribute Templates Ports Analysis Templates

Filter

Name	Description
ALARM	Alarmzustand
ALQC	Alarmquittierung berechnet
ALSTAT	Alarmstatus
ALSTATC	Alarmstatus berechnet
CAL	Kalibrierwert unkomprimiert
H	Grenzwert Warnung Tief
HH	Grenzwert Alarm Tief
HW Alarm Elem...	Zugehöriges HW-Alarm-Element in AF
T	
TT	
VALUE	

Delphin Digital Alarm Template

General Attribute Templates Ports Analysis Templates

Filter

Name	Description	Default Value
ALARM	Alarmzustand	0
ALQC	Alarmquittierung berechnet	0
ALSTAT	Alarmstatus	0
ALSTATC	Alarmstatus berechnet	0
Sensor	Zugehöriger Messfühler	—

HW Alarm Template (dig. Alarm)

Several Sensor templates each with Alarm Attribute

Event Frame Template

RIPIN Alarm Template

General Attribute Templates

Filter

Name	Description	Default Value
Acknowledge	Alarm Acknowledgement Information	
Comments	Alarm Comments	

Event Frame Template With String Attributes for Ack and Comment

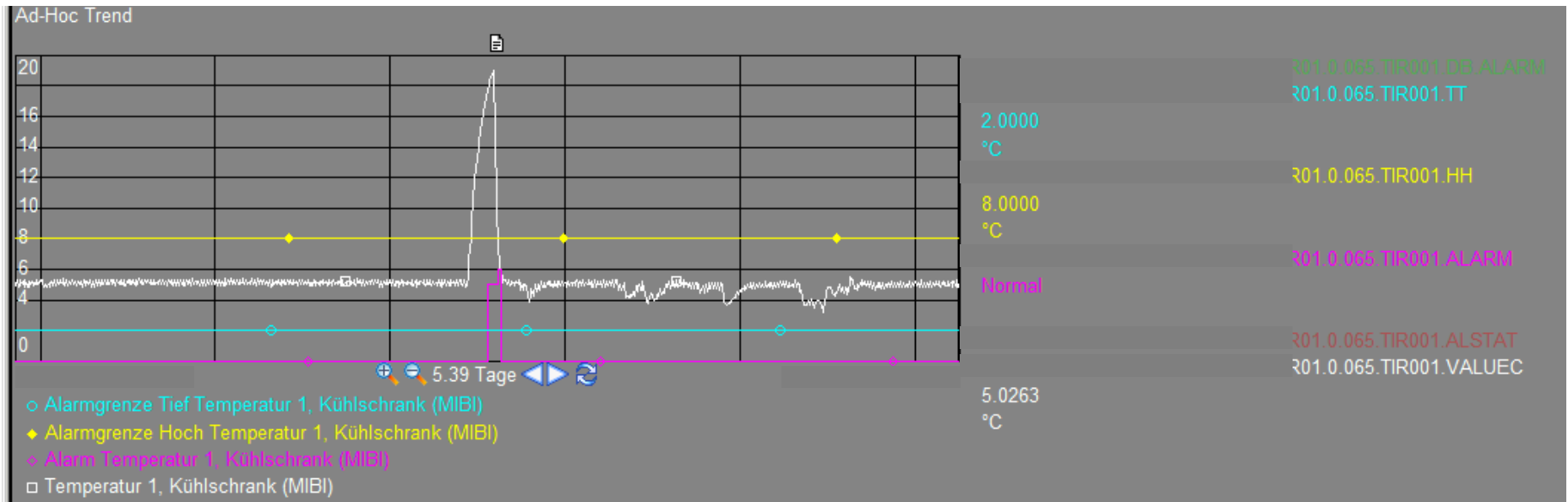
Event Frame Template With String Attributes for Ack and Comment

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

- 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:

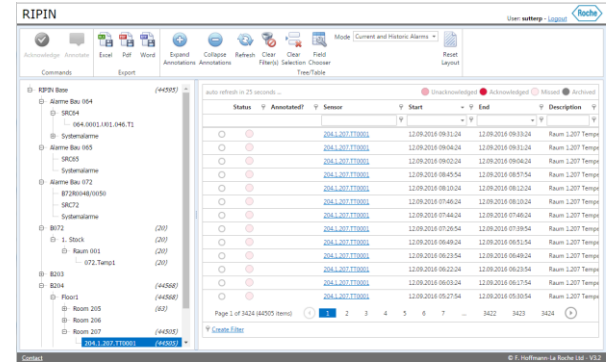
RIPIN

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 OSIssoft 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

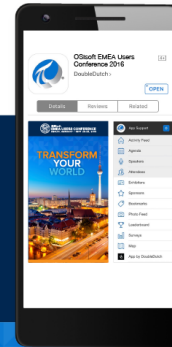
Please wait for the **microphone** before asking your questions



State your **name & company**

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谢谢

Danke

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado



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