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## ACHIEVING SERIALIZED PRODUCT TRACEABILITY FOR QUALITY & SAFETY

Facing Compliance Requirements in the Pharmaceutical Industry  
and Personal Liability of the Management

Joachim Misdorf  
CEO DataSquare  
Hamburg, Germany





**Deutsche Blister Union**  
(German Blister Union)

## Problem:

- In 2009 we had 15 million hospital patients and 25 million in old people's retirement & nursing homes worldwide (source: wikipedia)
- Most of these patients need medication every day

## Current solution:

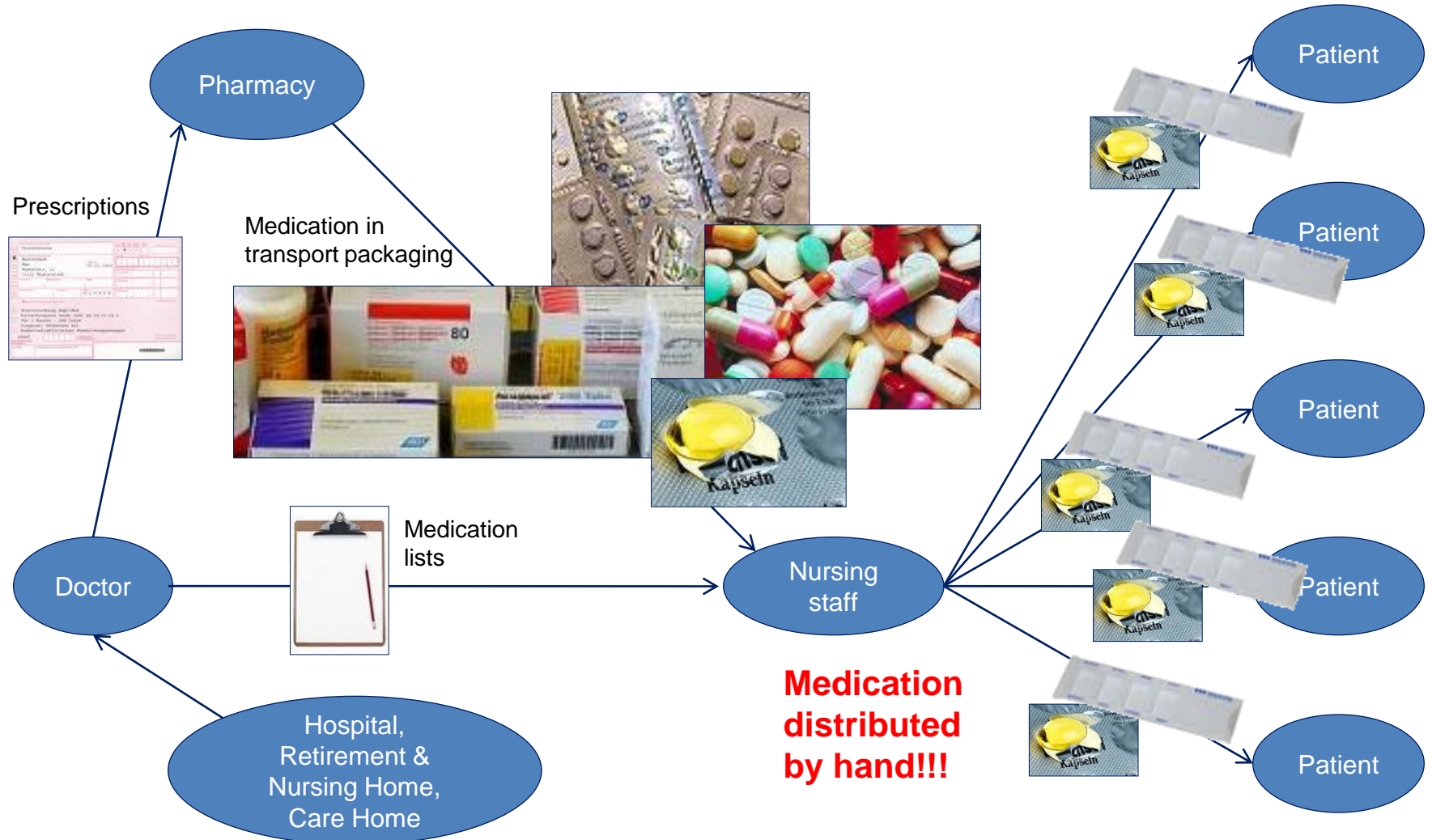
- Thousands of nurses put pills into small pillboxes by hand every morning

## Consequence:

- Procedure is very expensive
- High Error Rate: Patients become ill or even die due to medication or dosage errors



# Existing Process of Medication Supply



The risk for the CEO and the entire management is:

Up to

**lifelong prison terms** (US = lifelong / Europe = 10 years)

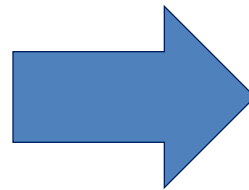
plus

**full personal financial liability** (worldwide)

for failure to follow the regulations for medication supply

- US Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- Plus local laws

# What Does „Blistering“ Mean?



- Solid, oral medication are provided in a one-week dispenser
- ➔ Patient-individual medication supply
  - Name
  - Date & time
  - Kind of drug



- Capacity per site: Minimum 3,000 patients/week
- Total capacity of the DBU network: Approx. 60,000 patients/week (Expansion stage 1)
- Quality Assurance: Use of video scanners (each blister pack is photographed, analyzed and archived)
- Drug safety: Patient information leaflet and tablet photo service
- Training: Comprehensive training courses for nursing staff, patients and their relatives

# Serialized Unit Packaging Information

Name & date of birth  
of the patient

**Musterfrau Angelika** ^

geb. am: 18/11/1917  
Festhelm

Station 1

**Mittwoch**

verw bis  
09/09/09 **12:00**

Dosage & name of  
the drug

1 **Tic Tac Orange**  
OBLONG ORANGE

schlaftabl

← Hospital ward

← Date & time of taking

← Kind of drug



DBU - Deutsche Blisterunion 19061 Schwerin  
Eckdrift 41 0385 55573362

Nr.:  
1010180102647  
BJ\_4547499\_N\_090909\_0003 31972

← Product Code for  
Aras Innovator

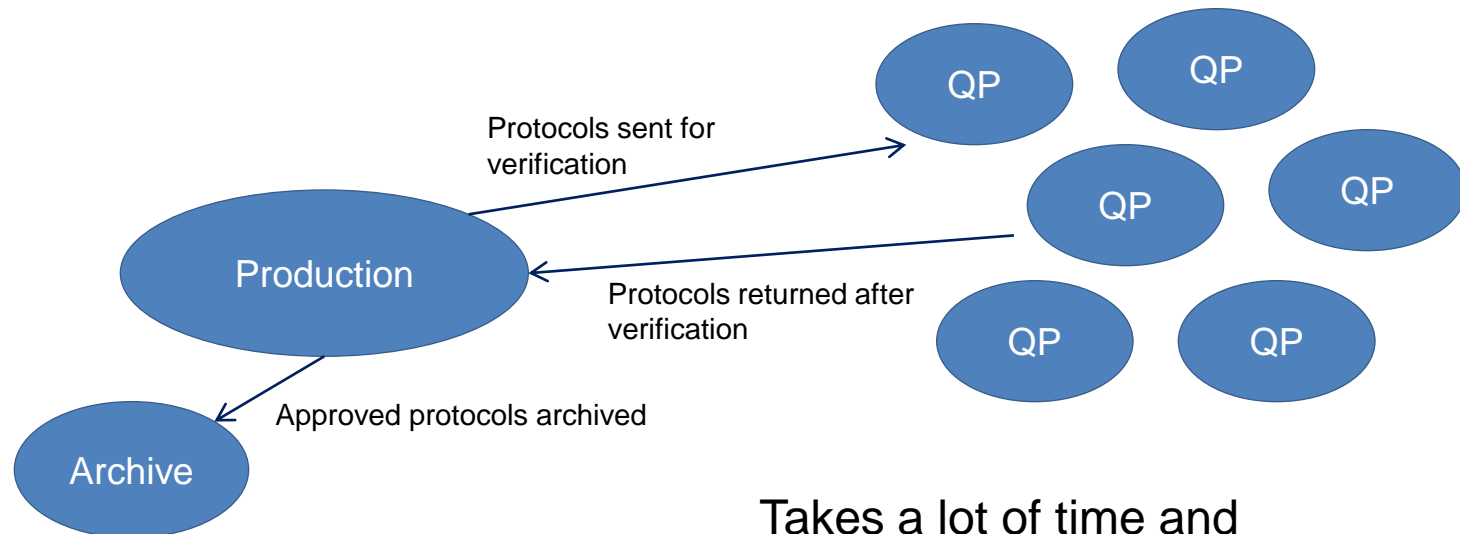


- Service provider of dose-dispensed medicine
- Germany-wide merger of blister pharmacies, regionally operating blister centers and industrial companies
- Offers service on all aspects of the mechanical blistering of drugs for the individual patient
- Founded in 2008
- 32 blister centers all over Germany in 2011
- Market activities in the US since 2011



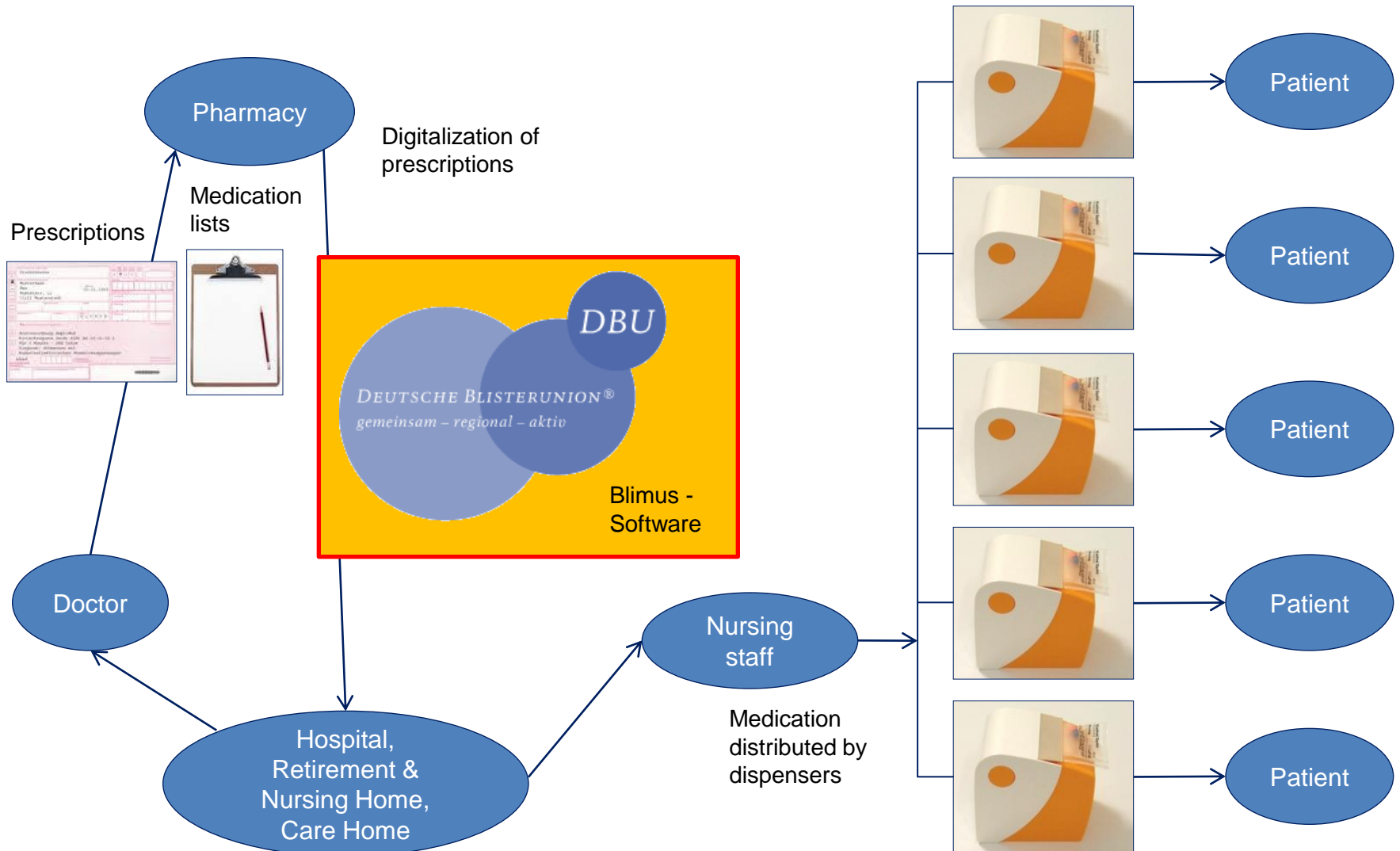
# Old Verification Process in Blister Pack Production

- Documentation of the production process with production protocols
  - Distribution to “qualified persons“ (QP) throughout Germany
  - Protocols verified by QPs
  - QPs sign the protocols by hand to signify approval
  - Archived for over 10 years or for life / amount of paper increasing substantially



Takes a lot of time and  
very inflexible!

# New Process for Medication Supply



- Care facility
  - Safe provision of medication
  - High level of medication safety
  - Lower stock of medication at the nursing station
  - Automated range calculation, coordination of prescription management
  - Patient-individual monitoring of medication for interactions
  - Increased pharmaceutical safety
  - Return of blister packs while complying with legal privacy requirements
  - Lot tracking of each individual blister pack
- Patient
  - High level of medication safety
  - Easy, convenient administration
  - No confusion between medications or dosage times
  - Continuous dosage and timely reminders of necessary prescription refills
  - Simpler control of the time of administration and dosage
  - Greater mobility and flexibility (vacation blister packs)

- **Ensurance of legally valid signature**
- **Integration of a signature component**
- **Re-writing of parts of the old software**
- **A very tight time table**

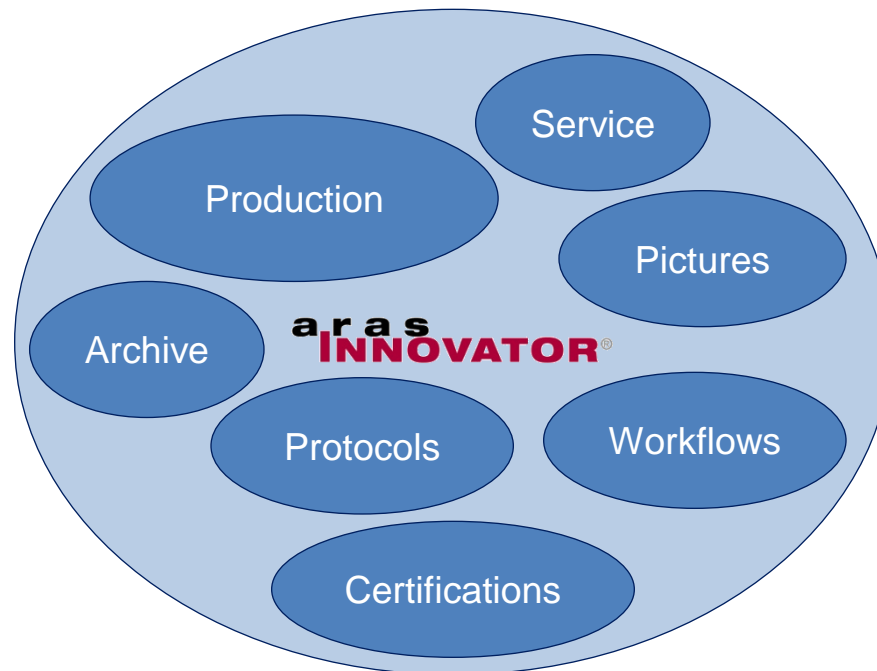
## → **Development of the Aras Innovator Signature Connector**

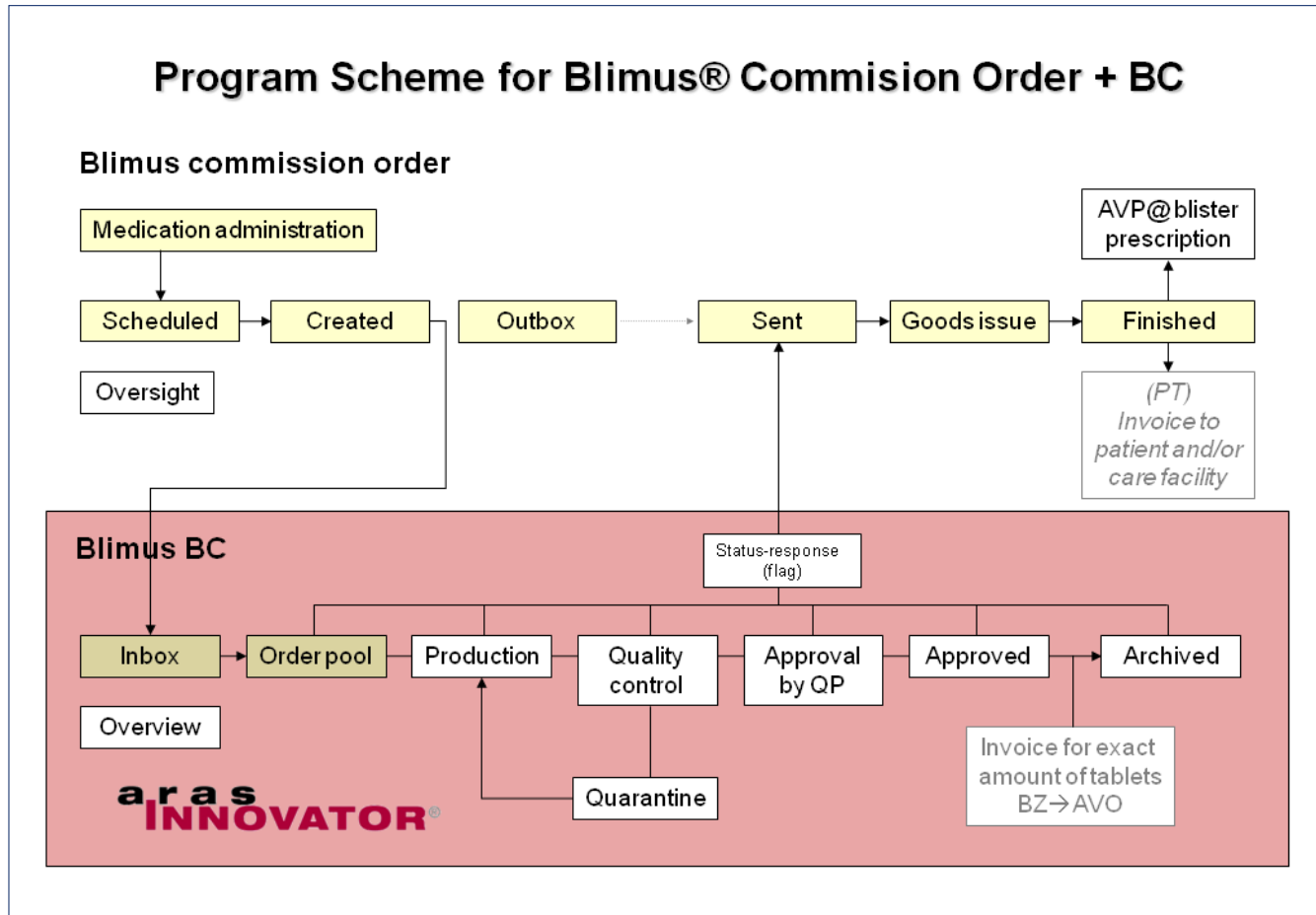
- Protocols can be provided with qualified electronic signatures for legally valid undersigning
- Signature software and hardware is integrated in Aras Innovator
- Signature process is controlled by Aras Innovator
- Operation through the Aras Innovator client and entry of a PIN code at the terminal

- **Automation of the production process**

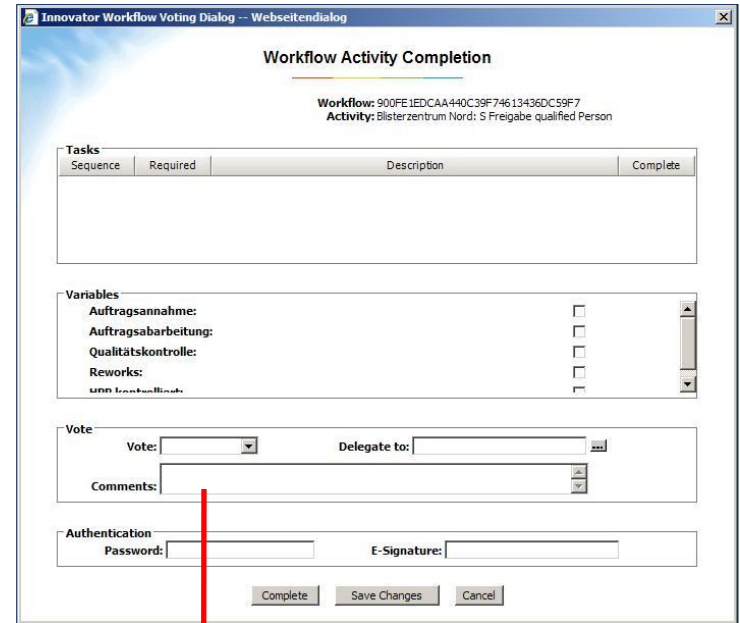
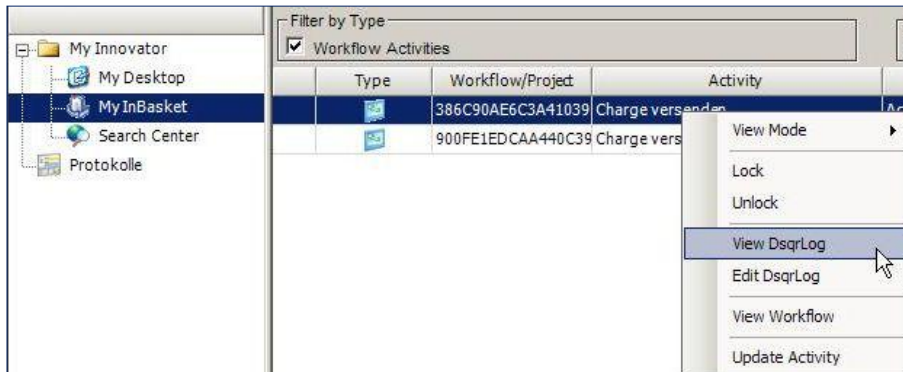
- Digital control and documentation of the verification and approval processes
- All-digital management and legally compliant archiving of the production protocols

➔ **Entire Data Management in Aras Innovator**



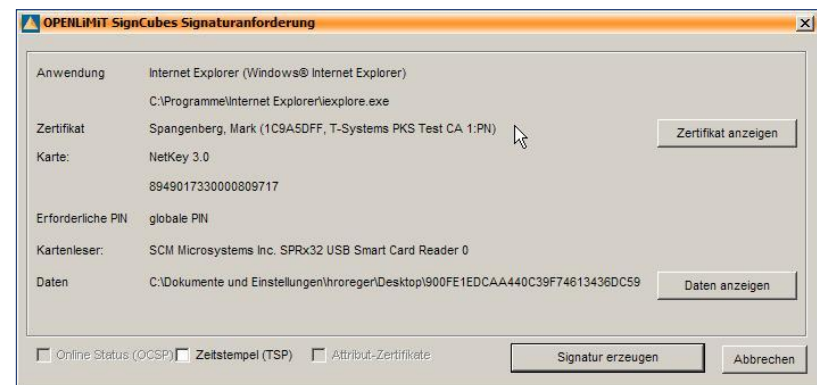


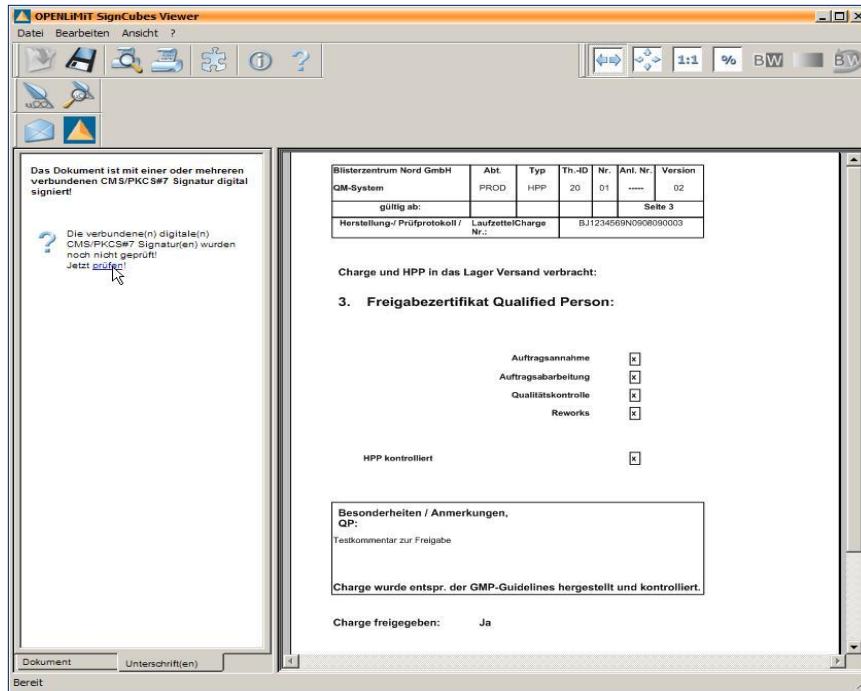
# Workflow Control in Aras Innovator





- Software approved by the Federal Office for Information Security (*Bundesamt für Sicherheit*)
- A batch is approved by a Qualified Person affixing authorized electronic signature to an approval protocol
- Aras Innovator clears the drugs for dispatch and initiates shipment of the specific batch via the workflow system; however, it does not create the signature and is not able to check this
- The signature must be created and checked by certified software; OpenLimit SignCubes software is used in the Aras Innovator Signature Connector for this purpose
- Aras Innovator automatically accesses this software

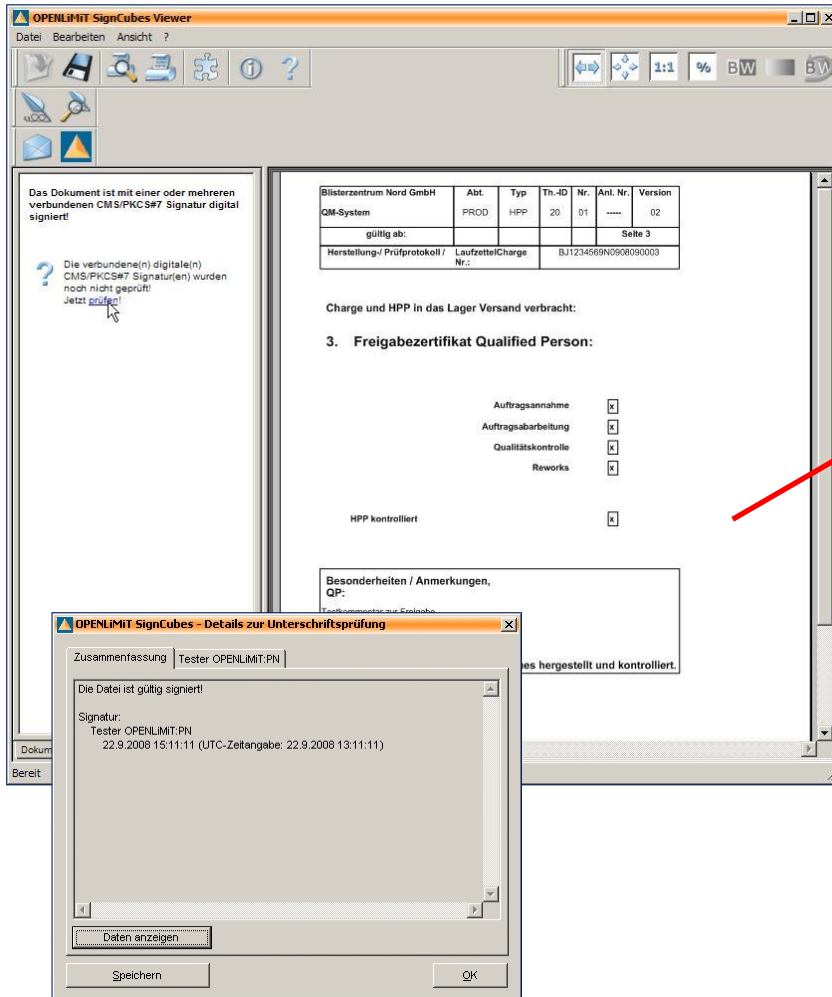




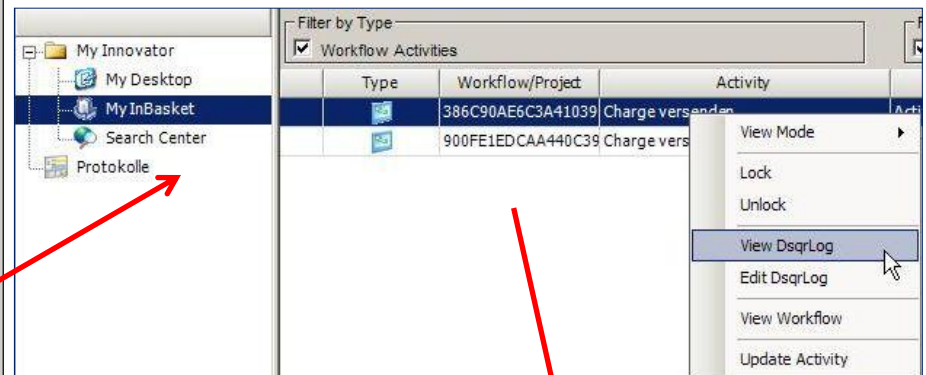
- A “container” is placed around the document; the signature is embedded in the container by the signature software  
(The hash value is encrypted by the smartcard's private key)
- The container becomes invalid if there is any subsequent interference
- This change is immediately recognized and notified
- International security certification: Common Criteria EAL4+

- The PIN code is entered via the smartcard terminal's keyboard
- The signature is created by pressing the green button after entering the complete PIN





Portrayal of the signature status in Aras Innovator lifecycle



Blisterzentrum Nord GmbH	Abt.	Typ	Th.- ID	Nr.	Anl. Nr.	Version
QM-System	PROD	HPP	20	01	---	02
gültig ab:			Seite 1 von 2			
Herstellung-/ Prüfprotokoll / Laufzettel Charge Nr.:			BJ_1234571_N_091009_0005			

**1. Herstellen von Wochenblistern am HD Medi- Blisterautomaten JV 400 SL (ACRS)**

Aufnahme Kundenauftrag in Blimus: Datum: ..... Uhrzeit: ..... Mitarbeiter: .....

Auftragsart:  Standard  Eilauftrag

Auftrag vom JV- Server übernommen:

STS- Tray- Protokolle ausgedruckt:

STS- Trays befüllt: Anzahl:

Line Clearance bei Tray- Abfüllungen (2. MA):

Verblistering gestartet Uhrzeit: .....

Aufgefüllte Kanister (Nr. + Uhrzeit):  
 .....  
 .....  
 .....

Verblistering abgeschlossen: Uhrzeit: .....

Besonderheiten / Anmerkungen, MA PROD:

Batch- Nr. Schlauchbeutelfolie:

Batch- Nr. Druckfolie:

Charge in Blimus zur Qualitätskontrolle freigegeben:

Blisterzentrum Nord GmbH	Abt.	Typ	Th.- ID	Nr.	Anl. Nr.	Version
QM-System	PROD	HPP	20	01	---	02
gültig ab:			Seite 2 von 2			
Herstellung-/ Prüfprotokoll / Laufzettel Charge Nr.:			BJ_1234571_N_091009_0005			

Besonderheiten / Anmerkungen, HL:

Charge wurde entspr. der GMP- Guidelines hergestellt,  
 Auftrag für QP- Freigabe bestätigt: Datum:

**2. Qualitätskontrolle**

Ergebnis Qualitätskontrolle: Rework?  ja  nein

Richtigkeit Kennzeichnung:  ja  nein

Fehlerjob- Nummern: .....

Neue Job- Nr.

Rework

abgearbeitete Fehlerjobs:

Ergebnis Qualitätskontrolle: Rework?  ja  nein

Richtigkeit Kennzeichnung:  ja  nein

Kopie Beispielblister (Kontrolle Richtigkeit Kennzeichnung) beigelegt und sonstige Anhänge eingescannt und dem Blimus- Protokoll hinzugefügt:

Besonderheiten / Anmerkungen, KL:

Charge wurde entspr. der GMP- Guidelines kontrolliert,  
 Auftrag für QP- Freigabe bestätigt: Datum:

HPP (Seiten 1+2) in DMS eingescannt und QP zur Freigabe zugeordnet

Datum:  Uhrzeit:

Charge und HPP in das Lager Versand verbracht:

# Re-entry of Paper Protocols

Blisterzentrum Nord GmbH	Abt.	Typ	Th.- ID	Nr.	Anl. Nr.	Version
QM-System	PROD	HPP	20	01	---	02

gültig ab: Seite 1 von 2

Herstellung/J Pr...

**1. Herstellen**  
400 SL (AC)

**Aufnahme Kunde**

**Auftragsart:**

**Auftrag vom JV-**  
STS- Tray- Proto  
STS- Trays befüll  
Line Clearance b  
Verblisterung ge  
Aufgefüllte Kanis

.....  
.....  
.....

**Verblisterung ab**

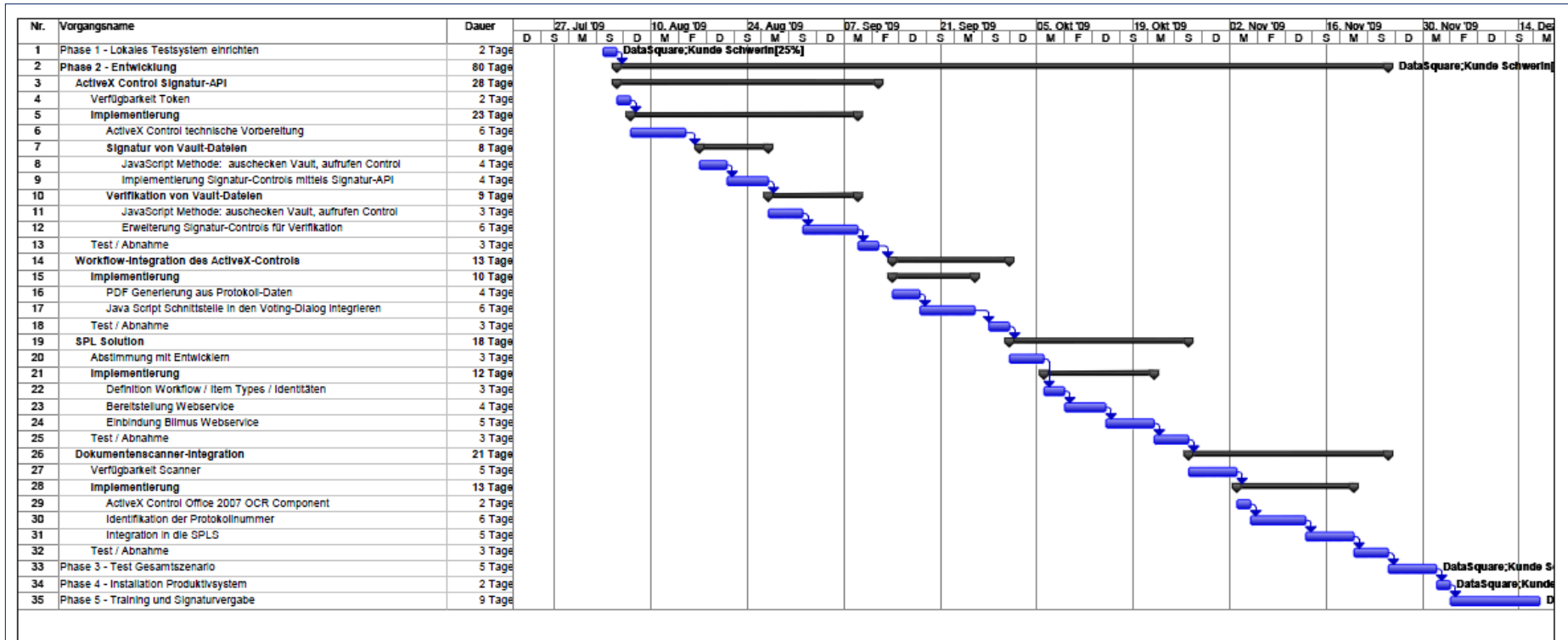
**Besonderheiten / Anmerkungen, MA PROD:**

**Batch- Nr. Schlauchbeutelolie:**  
**Batch- Nr. Druckfolie:**

Charge in Blimus zur Qualitätskontrolle freigegeben:



- Automatic text recognition by OCR
- Protocols automatically allocated and sorted in Aras Innovator by code recognition
- Data automatically saved in Aras Innovator



In comparison to other PLM Systems: 2 to 3 times faster!

- **Management**
  - Centralized control and monitoring and therefore speeding up of all processes
  - Orders distributed to DBU blister centers throughout Germany depending on their workload
  - Time and costs minimized
- **Resources**
  - Qualified Persons (QPs) very expensive
  - Several blister centers served by one QP → cost sharing
  - Orders rapidly transferred to other QPs in the event of illness or holiday
- **IT**
  - Central hosting
  - Low maintenance requirement and less expense
- **Legal requirements**
  - Personal liability of the entire management
  - Medical technology is shaped by a very large number of legal requirements
  - The personal signature of a QP is required by law
  - Legal obligation to retain documents for 10 years
  - Ongoing audits by the Association of Statutory Health Insurance Physicians (KV) and Health Ministries
- **Operation**
  - Unskilled staff can be employed in the Blister Center
  - Significantly less paper
  - All orders processed faster





# *DataSquare*

YOUR DATA MANAGERS

## Many Thanks for your Attention

Your DataSquare Team

DataSquare GmbH & Co. KG

Hamburg/Germany

[info@datasquare.de](mailto:info@datasquare.de)

[www.datasquare.de](http://www.datasquare.de)

