



DOQ

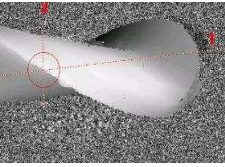




Die Papierlose Fabrik

DOQ Presentation

- Design & Development
- Moduls
- FDA/GMP/Part 11
- Worth Knowing
- Key Benefits

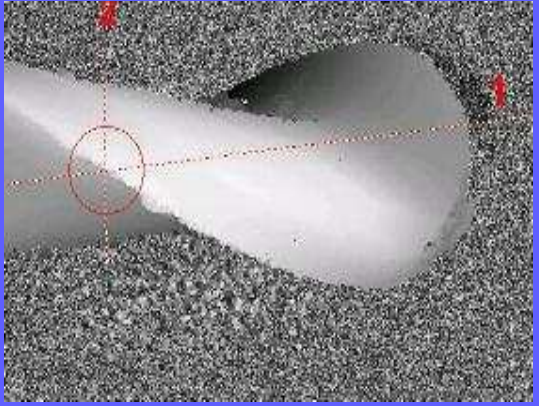
DOQ Design & Development (Important Milestones)

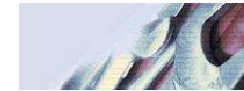
Januar 2004	1. Biomedical Customer "Merix"
October 2003	DOQ entering open market outside Med. Completion "Modul Biomedical"
September 2003	FDA (Part 11) electronic Signature
August 2003	DOQ in Business Unit RV (Erlangen)
March 2003	DOQ in Business Unit RS (Chicago-Erlangen)
February 2003	FDA- (Part 11) compliant
March 2002	DOQ Customizing for Siemens Med. Business Unit CTD
June 2000	DOQ in China (Shanghai)
December 1999	DOQ P10 Electronic DHR in CT Factory



DOQ Modules

- „Configuration“ Module ⇨ Modeling of complex production processes (including suppliers)
- Module „Process Control“
- Module „Form Manager“
- Module „Serial Number Format Generator“
- Module „Electronic Signature“
- Module „Archive“
- Module „Scanning“
- Module „Maintenance“
- Module „Interface“
- Module „Analysis“





Configuration Modul / Process Controlling Module



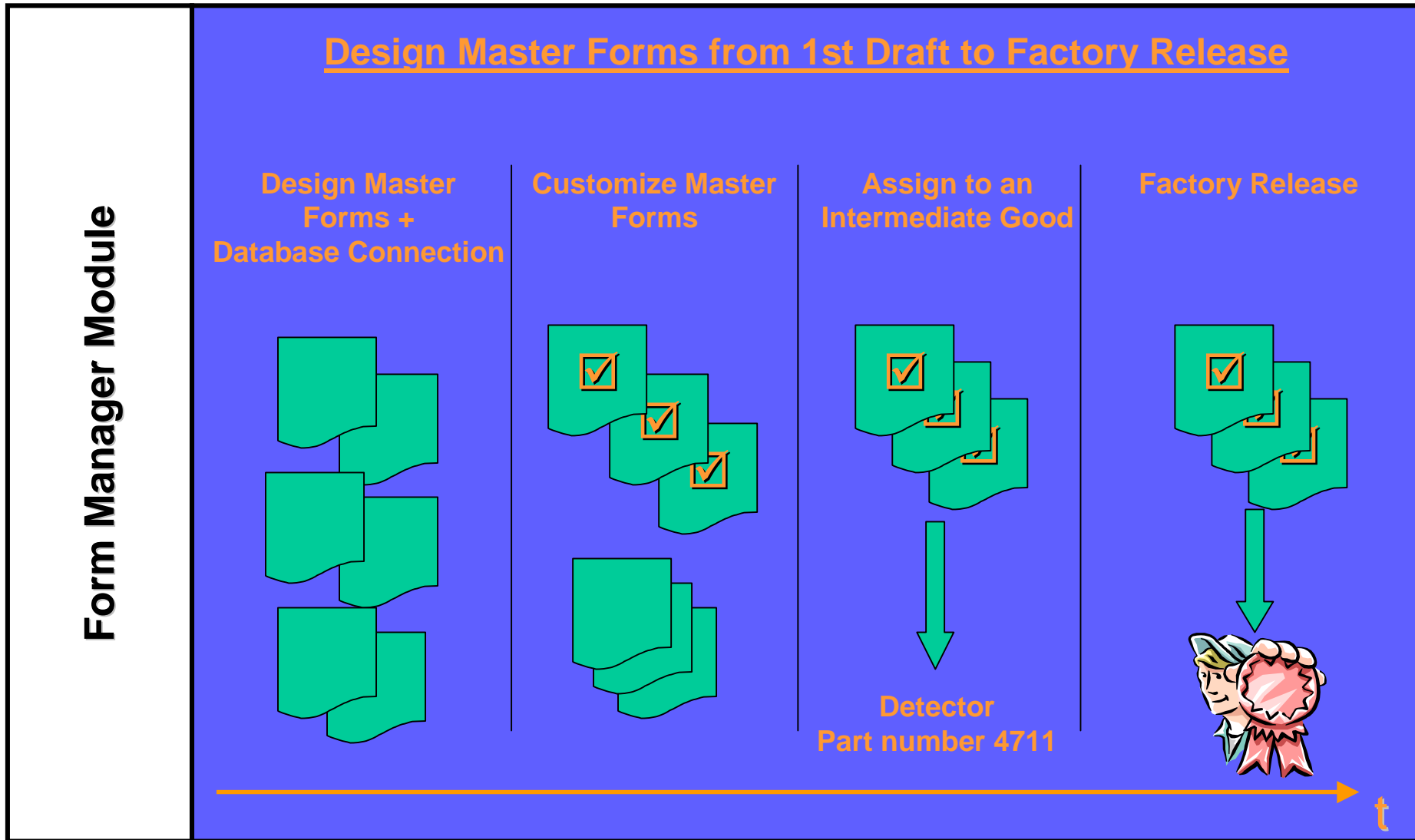
- The „Configuration Module“ assists in modeling the production process of the ceramics detector (cf. image above). The boxes represent intermediate goods with n:1, 1:n und n:m relations in between.
- The example above shows a snapshot of an intermediate good that is currently in the production process of CTD (ceramics detector). DOQ depicts the progress of the process in real-time by the color of the boxes (green = finished; white = open; red = in quarantine).



Configuration Modul / Process Controlling Module

Module Description

- Implements a complex production process (factory, suppliers, ...)
- Allows data entry in master forms customized for each intermediate good
- Monitors chosen intermediate goods
- Monitors production non-conformances & distinctive features during the complete production progress of a good
- Visual Status control of intermediate/finished good
- Input of remarks (e.g. service message, notifications) for intermediate goods in the process (also displayed at later intermediate/finished goods)





Form Manager Options

Example Master Form „Ceramics Array“

507686889_FHR_003_01_01_0000000 : Formular

Keramikscheibe Scheibentechnik: CT-Werte

SNR/CHNR : 07686889/G357_03

APNR: 07020-MB1 Nur für internen Gebrauch Formularkopie ungültig :

1. UFC-Scheibenprüfung CCD-Kamera

Punkte / Scheibe:

Lichttaubeute Mittelwert: [CCD-Einheiten]

Lichttaubeute mittlerer Gradient:

2. UFC-Scheibenprüfung MOM

MOM-Prüfplatz:

Strahlungsdrift: [MOM-Einheiten]

Nachleuchten 1:

Nachleuchten 2:

3. UFC-Korngrößenprüfung (Probennahme im Randbereich der Scheibe)

Mittlere UFC-Korngröße (d50): [µm]

UFC-Feinkornanteil (d10): [µm]

UFC-Grobkornanteil (d90): [µm]

Form Manager Options

- Design form fields
- Enforce mandatory fields
- Definition of minimum / maximum constraints
- Integration of „drop down“ lists
- Open other files, e.g.:
 - ✓ Video-Files
 - ✓ Audio-Files
 - ✓ PDF-Files
 - ✓ HTML-Files
- Calculated fields
- Optional / mandatory fields
- Sibling fields
- Barcode fields
- Maintenance fields





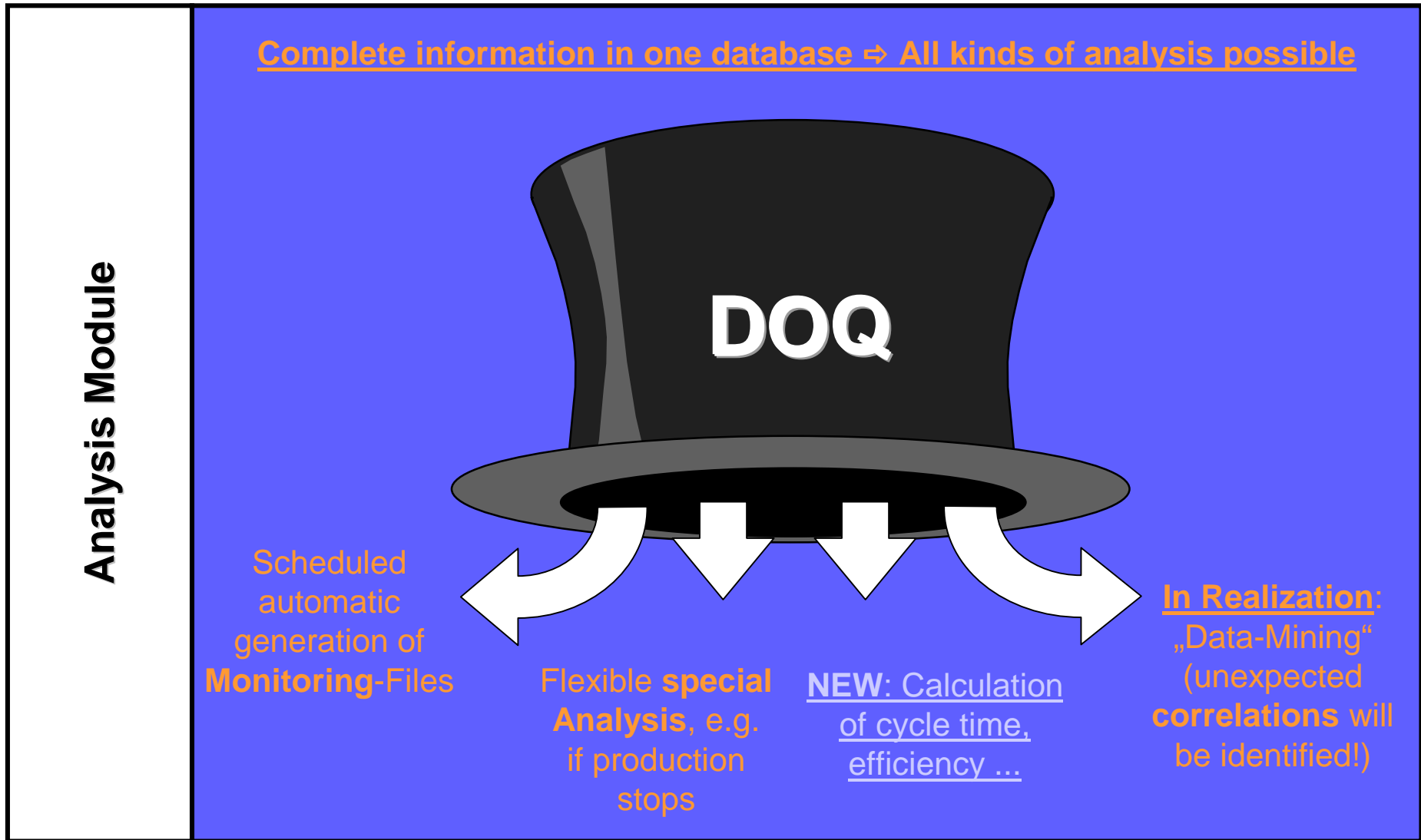
Electronic Signature Module





Worth Knowing: „Electronic Signature“

- Audittrail and Electronic Signature created for each input
- One Electronic Signature for one data input as well as for multiple data inputs (by one person)
- Currently about 1 Million Electronic Signatures in DOQ per Month
- Single Sign On

Archive / Scanning / Maintenance and Interface

- **Archive Module** 
 - Complete DHR/DMR Information stored in one database system
 - Archive formats: TIFF, PDF
 - Archiving possible in each security container (e.g. SAP EDM)
 - **Scanning Module** 
 - Document (papers) scan
 - Virtual Scan of electronic Files (PDF, HTML, ...)
 - **Maintenance Module** 
 - Status of Maintenance is displayed in each form view:
 - Work stations
 - Machines
 - Engines
 - **Interface Module** 
 - Input/Output Interfaces: SAP, Excel, SynGo (in realization), ...
- => Total amount of factory data is stored in one database system**



21 CFR 11

Welchen Einfluss hat die SW auf das (verkaufsfähige) Produkt?

3 Bitte geben Sie eine entsprechende Zahl ein.

1 = Keinen/Geringer Einfluss, z. B. Preise
 2 = Mittlerer Einfluss, z. B. Complaint-System, Prozessbeschreibungen
 3 = Hoher Einfluss, z. B. Schaltpläne, Produkt-SW-Code, Sicherheitsberechnungen

In welchem Maße ist die SW Part 11 compliant?

1 Bitte geben Sie eine entsprechende Zahl ein.

1 = Beinahe compliant
 2 = Mittlere non-compliance, z.B. Audittrail vorhanden, elektronische Unterschrift wäre nötig
 3 = Schwere non-compliance, z. B. fehlende Validierung oder Mängel in den pro...

Wie hoch ist die Erkennbarkeit?

3 Bitte geben Sie eine entsprechende Zahl ein.

1 = Niedrig
 2 = Mittel
 3 = Hoch

Priorität:

9

27 - 18	Prio 1
17 - 9	Prio 2
8 - 1	Prio 3

Screen dump
Part 11 questionnaire
"DOQ"

Since February 2003 DOQ is Part 11 Compliant

- ✓ Audittrails are implemented
- ✓ Archiving of all DHR/DMR-Information in SAP security container
- ✓ Electronic Signature (since September 2003)




Worth Knowing

- **Current DOQ Version: 5.0**
- **No extra SAP licenses for factory workers necessary**
- **Short training period (worker = approx. 1,5 h)**
- **Customers**
 - ✓ **Internal customers: Business Units CT, CTD, RV, RS (⇒ Erlangen / Chicago)**
 - ✓ **External customers : Merix, Scanditronics (in realization)**
- **1 Million Electronic Signatures (Feb. 9th – Mar 12th)**
- **Multi Language Interface English/German (optional „Chinese“)**
- **22% of all external DOQ sales go back to Siemens Medical Solutions**



Worth Knowing

- Status tracking for each process step and intermediate/finished good
- Visual representation of 1:n/n:1/n:m relations for all process steps and intermediate/finished goods (serialnumbers/batches)
- Integrated maintenance system
- Distinctive feature & non-conformance data entry system
- “Sibling field” system (provides ergonomic input of large amounts of data)
- One PC for several workers (reduction of logon/logoff time, reduction of PCs in the factory)
- Analysis Module for „Regular“, „Special“ and „Data Mining“ Analysis



- Significant increase of process quality
- Reduction of flawed goods / reworking
- Overall cost reductions
- Easy integration of new product/assembly (-lines)
- Optimized support for data input (no redundancies)
- FDA – 21 CFR Part 11 Compliance
- Close to 100% paper reduction
- Standardized electronic archive
- Various reporting/evaluation modules
- Various interfaces