

Meeting professional group medical technology

Jüke Systemtechnik GmbH

Altenberge

28.11.2017

Welcome!

Meeting professional group medical technology

Jüke Systemtechnik GmbH, Altenberge, 28.11.2017

Agenda

Dienstag, 28. November 2017		
11:00	Welcoming and Introduction of the Participants	
11:15	Development and Production Processes at a Medical Technology System Supplier	Martin Hovestadt Jüke Systemtechnik GmbH, Altenberge, DE
11:45	Neural Implants in Basic Research and Clinical Application	Dr. Ulrich Friepp Fraunhofer ITEM, Hannover, DE
12:15	Guided Tour through Jüke Systemtechnik GmbH	
12:45	Lunch Break	
13:45	Energy autonomous implants with feedback controlled electrical stimulation	Prof. Dr.-Ing. Dennis Hohlfeld Universität Rostock, Rostock, DE
14:15	Discussion about "Challenges in Production and Distribution of Active Implants"	
15:15	Self presentation of the Focus Group	
15:45	Discussion about future activities of the Focus Group	
16:15	Network News	
16:30	Outlook on the next Focus Group Meeting	
17:00	End of the Event	

Development- and Production-Processes of a System Supplier in Medical Technology

Dipl.-Ing. Martin Hovestadt

CEO

Jüke Systemtechnik GmbH, D-48341 Altenberge

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- 1. Short presentation of Jüke Systemtechnik**
- 2. System supplies as partner for the Medical Technology Industry:
Process chain to the final system**
- 3. Processes at Jüke – development and implementation**

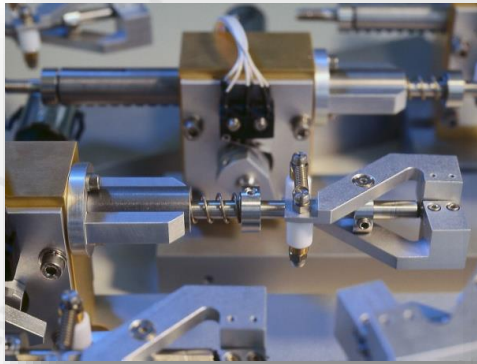


Company

Company:	Jüke Systemtechnik GmbH
Foundation :	1990
Business:	Mechatronic-System supplier
CEO:	Heinz Jürgens, MBA + Martin Hovestadt, Dipl.-Ing.
Location:	D - 48341 Altenberge, near Münster, NRW

System supplier for mechatronics

- Development and engineering
- Production and manufacturing
- Assembly of systems and components
- Logistics and material management
- Processes according to DIN EN ISO 9001 und DIN EN ISO 13485



Our references

OLYMPUS

sirona.
The Dental Company



GE Healthcare

Thermo
SCIENTIFIC



CARL ZEISS MEDITEC



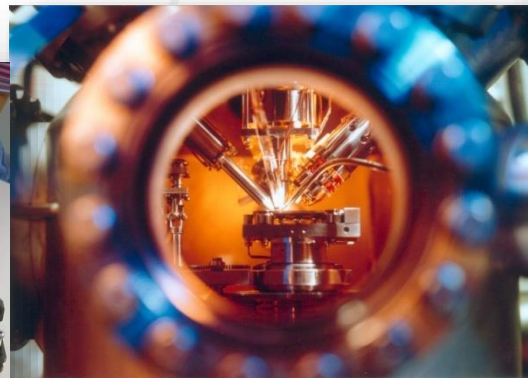
strattec ● ●
biomedical systems

Drägermedical
A Dräger and Siemens Company

KNAUER
The KNAUER logo graphic, featuring a blue stylized waveform or signal line above the word 'KNAUER' in blue capital letters.

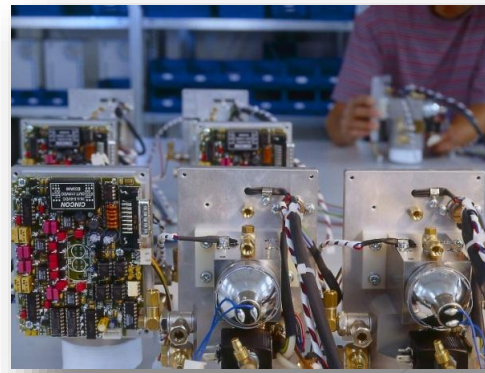
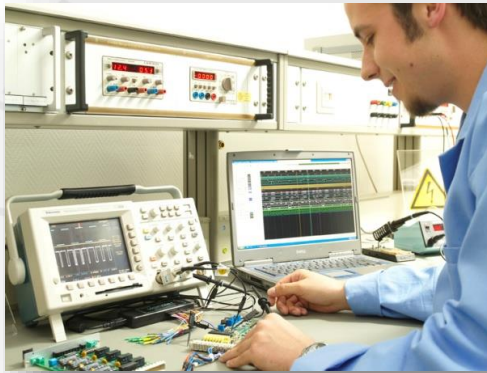
The industries of our customers:

- **Medical technology**
- **Optical technology**
- **Analytical-, Bio- und Laboratory technology**

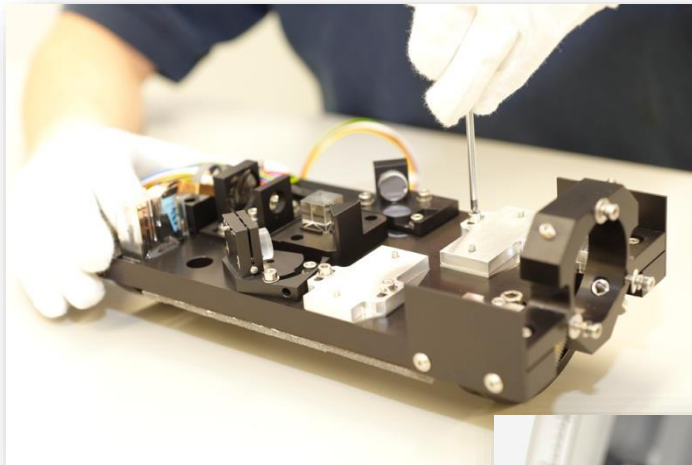


Core competences

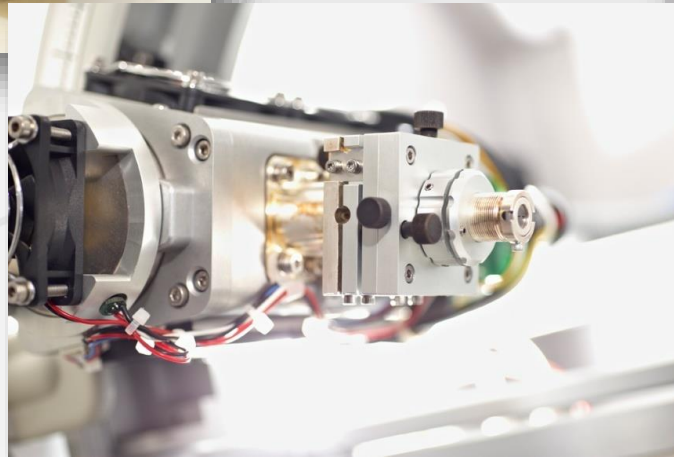
- **Product development and engineering of assemblies, modules and systems**
- **Contract manufacturing for devices with complete logistics**
- **Flexible production and processes for small batches**
- **Support over the entire product life cycle**



Assemblies and systems



**Optical unit for
laser systems**



**X-ray
diffractometer**

Assemblies and systems



Optical system for skin cancer diagnostics

Synthesizer for radio pharmacy



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3. Processes at Jüke – development and implementation

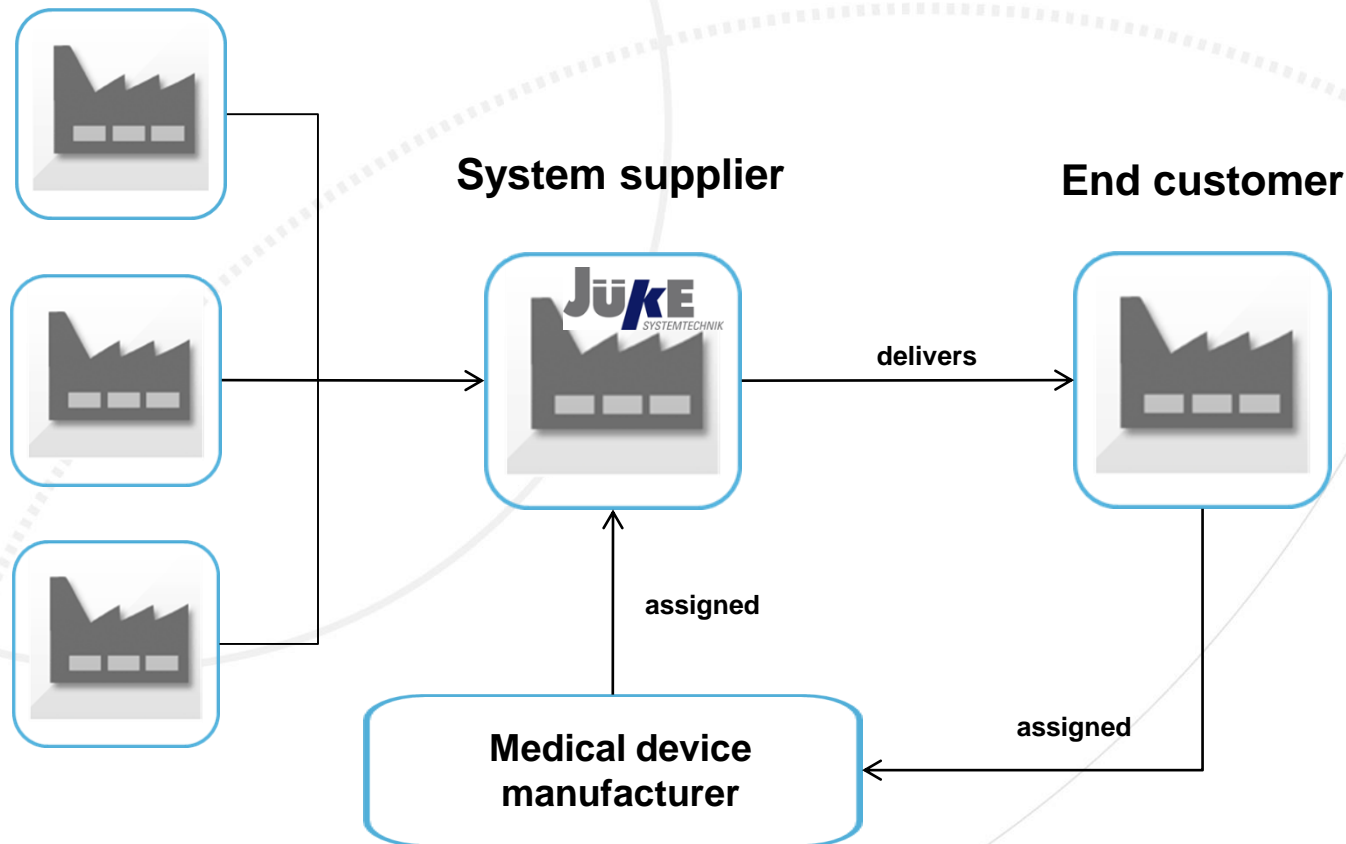
Current challenges for medical device manufacturers

- **Reduced product life cycle periods**
- **Increasing R&D-costs**
- **Increasing specialization in components und systems**
- **Smaller batches**
- **Increasing component diversity and variety**
- **Exploding documentation effort**
- **Increasing regulatory requirements and standards**
- **More complex processes and more complex supplier structures**
- **Staff problem / lack of skilled workers**

Process chains – Concepts for the medical technology industry

- **Expansion of the entire process chain in the own company**
- **Development / expansion of processes with reliable subsuppliers**
- **Integration of engineering partners**
- **Establishment of a long-term partnership with system suppliers**
- **Relocation of development and production processes, especially for those products that belongs not to the own core competence**

Typical supply chain concept



Advantages of cooperation with system suppliers

- Professional partners with special process know-how in production and development
- Faster development cycles with more flexibility and better access to external capacities in engineering and production
- "Complete solutions" from one partner → efficient process due to less interfaces
- Cost transparency in all steps from product development to series production
- no establishment of long-term fixed costs in equipment and personnel
- Reduction of process diversity and complexity
- Benefit from engineering experience from other medical technology projects

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3. **Processes at Jüke – development and implementation**

Our process structure

Control processes – core processes – supporting processes

1. Prozesslandkarte



2. Prozessmatrix

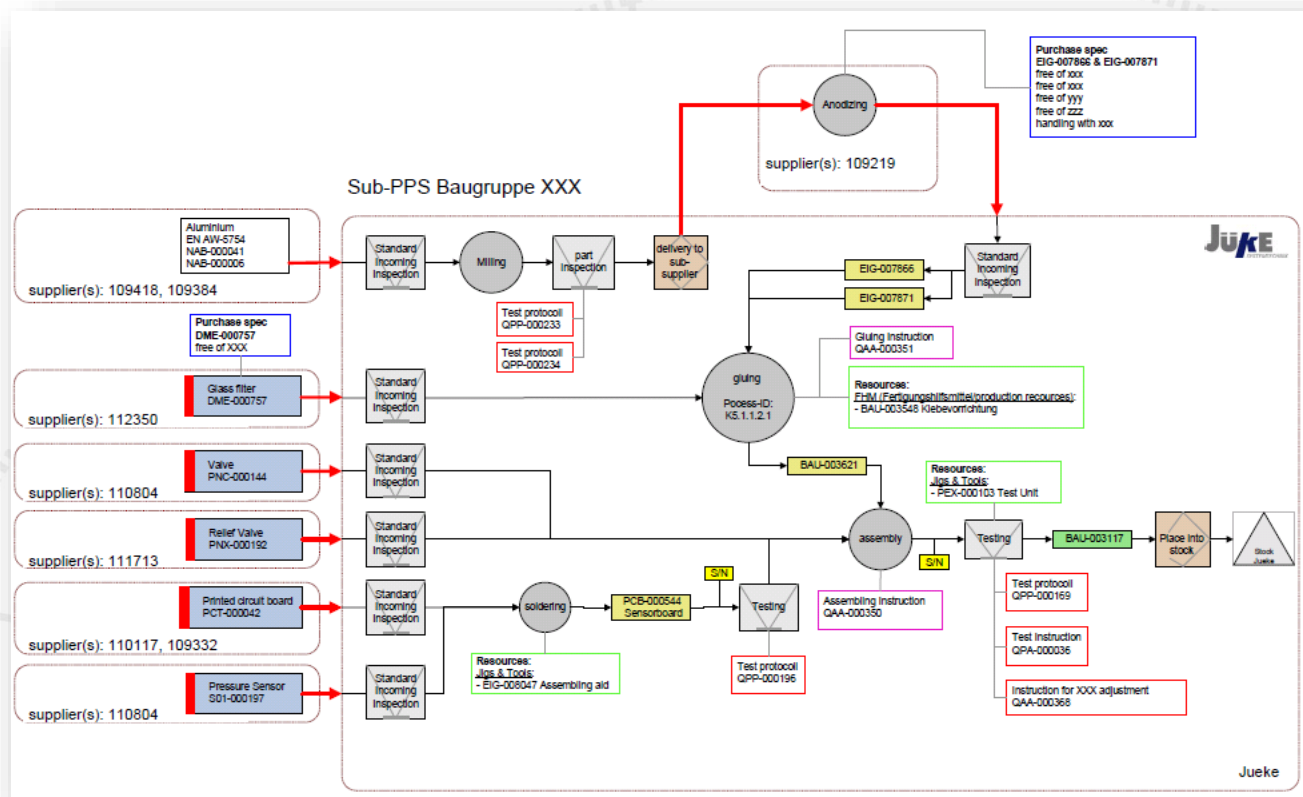
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			GL	VW	FR	VT	QM	IT	AS	LG	EW	PK		
K1	Vertrieb	QVA-000018				V					M	M		
K1.1	Angebotserstellung	QVA-000125				V					M			
K5	Produktion									I	M	V		
K5.1	Montage	QVA-000007									M	V		
K5.1.1	Kleben	QVA-000045									M	V	X	
K5.1.1.1	Sekundenkleber	QVA-000048									M	V		
K5.1.1.2	2-Komponenten-Kleber	QVA-000051									M	V		
K5.1.1.2.1	Kleben Bauteil XYZ (BAU-002621)	QVA-000052									M	V	X	

Product and process introduction for new products

- Development of a product and process structure (PPS)
- Preparation of a risk analysis for the production of this new product
- Definition of critical processes (internal + external), required equipment, devices and test equipment
- Defining of new, possibly validated processes / sub-processes
- Planning of production and test equipment



Typical product and process structure: sub assembly XXX



Advantages of using the product and process structure (PPS)

- **Simplification of complex processes through visualization**
- **Critical process steps become easier to see**
- **Overall connections are clearly visible**
- **Ensure the same information stand in the discussion during risk analysis + planning**
- **Overview of required production resources, devices, test equipment and documentation without access to complex ERP system functionalities**
- **Support in the modularization of processes**

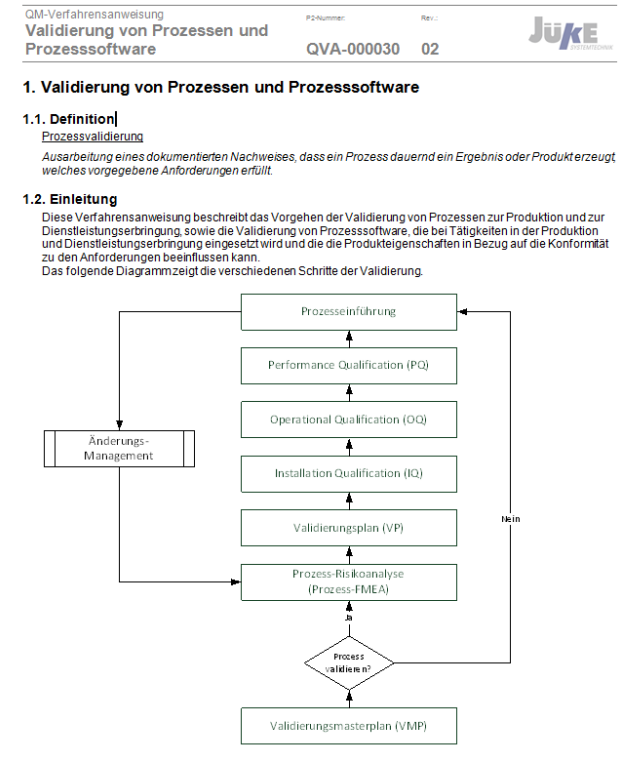
Validation of processes

Preparation of a documented verification that a process permanently produces a result or product that meets specified requirements

(Source: ZLG, Basic Requirements, 3.9 B18)

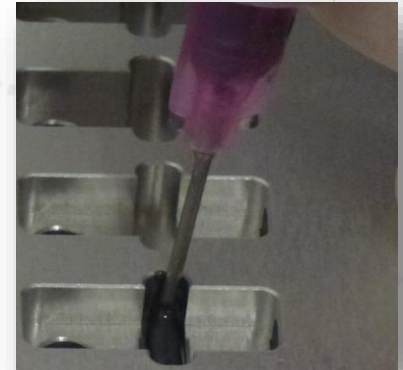
- Installation Qualification, IQ
- Operational Qualification, OQ
- Performance Qualification, PQ

- Validation masterplan
- Specification sheet process
- Process risk analysis
- Validation plan



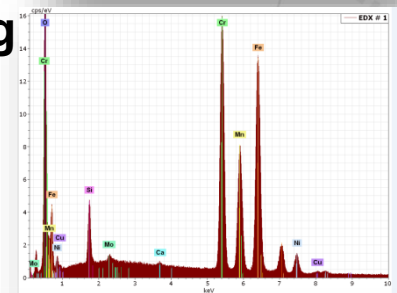
Process validation: Gluing process as an example

- **Specification of the individual gluing procedure**
- **Risk analysis: execution / extension of an existing RA explicit for this product**
- **Validation plan**
 - IQ: gluing device, instruction, staff training
 - OQ: Execution of gluing test series to determine the process control and intervention limits
 - PQ: Observation of the gluing process over a longer period, performance qualification
- **Approved through an overall product audit together with the customer**



Process validation: New introduction of laser welding (4-axis)

- Introduction of the laser welding process for universal use in production (4-axis)
- Extensive installation qualification of the laser welding machine (machine, training, maintenance, etc)
- Own test series to determine the area of application including metallurgical investigations
- Creation of programming and process standards
- Modular process design
- Execution of OQ and FQ on defined assemblies

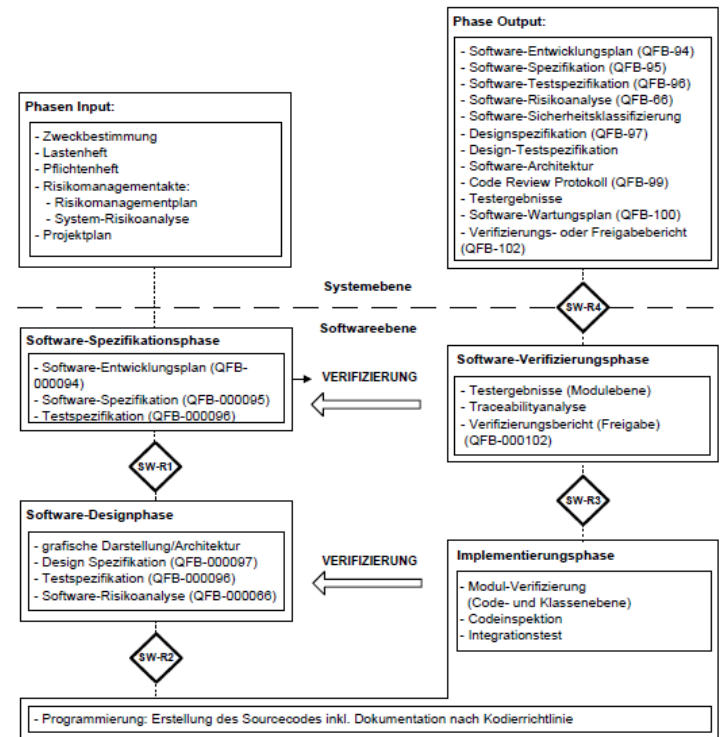


Process example: Software development according to DIN EN 62304

- Specification phase
- Design phase
- Implementation phase
- Verification phase
- Design-Transfer
- Production phase
- Market phase
- Closing

4 Softwareentwicklungsphasen

4.1 Vorgehensweise



Process example: Supplier management (control process S5)

- Around 500 active sub supplier and service partner
- Approval procedure for a new registration at service providers and key component suppliers
- Regular evaluation according to defined criteria in the ERP system (A-B-C analysis)
- Supplier visits and audits
- framework agreements
- supplier information
- Supplier support and development

QM-Formblatt / QM-Form
Lieferantenselbstauskunft
Supplier Questionnaire

JUKE

General Information Allgemein

Company name Name der Firma	
Street Straße	
ZIP-Post code, city PLZ, Ort	
P.O. Box Postfach	
Country Land	
Legal form Rechtsform	
Internet Internet	
Language Korrespondenzsprache	
Year of foundation Gründungsjahr	
VAT ID USt-Identifikationsnummer	
Banking Institution Geldinstitut	
Account no., Kontonummer	
BCN Bankleitzahl	

Contact person Ansprechpartner

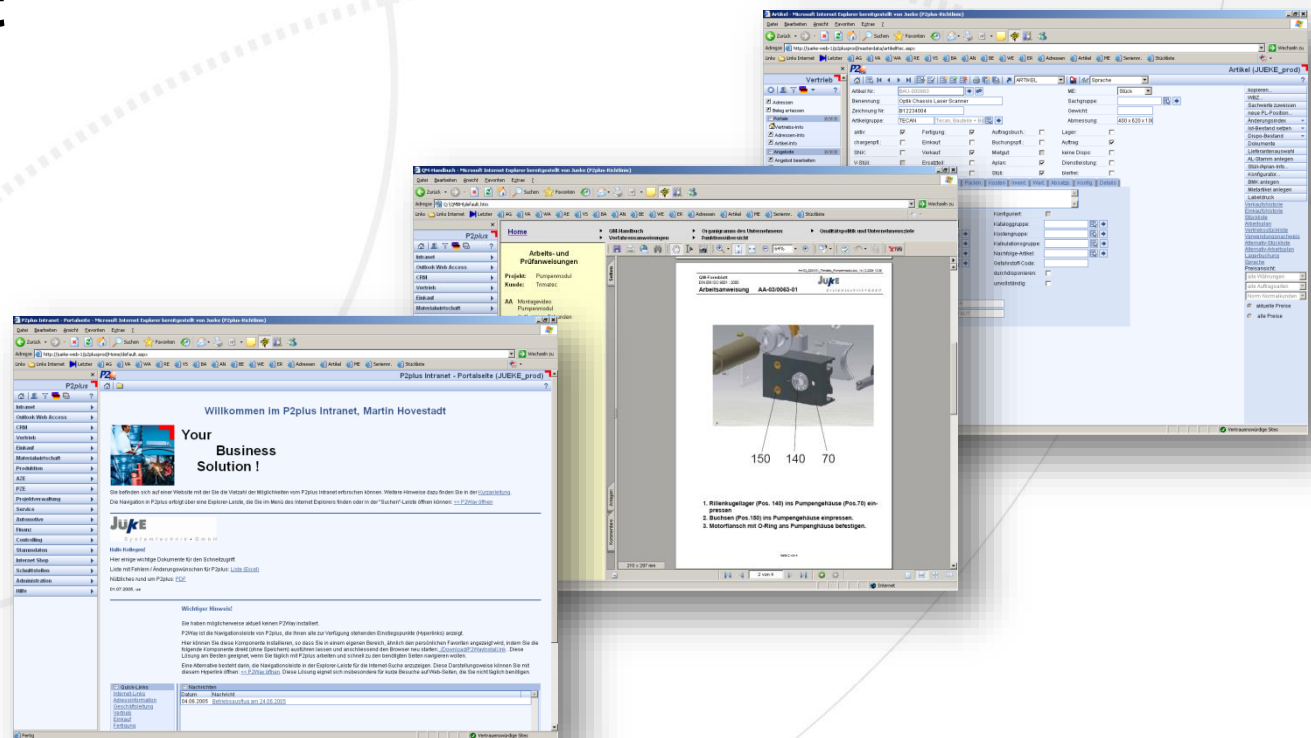
Surname, first name Name, Vorname	
Direct phone Durchwahl	
eMail E-Mail	
Fax	

Number of Employees Anzahl Beschäftigte

Administration Verwaltung	
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The basis of an efficient process structure in the company is an modern and integrated information management

- ERP-System
- PPS-System
- CRM-System
- DMS-System
- Workflow
- Intranet



Discussion points for the meeting

- **What are the (current) technical challenges?**
- **What are the challenges regarding admission (and organization)?**
- **What are the challenges in marketing and sales?**
- **How and where can IVAM help?**

**Thank you very much
for your attention!**