



**Information notes for
customer and works meetings Q2 2017**



**A brief information
about [.-ING]'s
organizational
development**



Idstein / Ts. (Germany), 01.03.2017
Dipl.-Ing. B. Geis and I. Wagner (M.Sc.)

Information notes regarding

- **Our guiding principle**
- **Being in good company**
- **Professional engineering & consultancy services**
 - Process Engineering & Validation
 - Systems Design & Engineering
 - Project & Quality Management
- **Graduate School & Institute**
 - BiochemPE matters and „Course X“ concept
 - Modules & seminars
 - Institute's research, development and competence clusters
- **Implementation & improvement program**

Activating Knowledge ...

"Everything we do we believe ...

- science and technology matters to our Quality of Life, and
- engineering knowledge is the vital raw material for shaping the future
- because success is made by ingenious and committed people."



Creating Values ...

"The way we do is to ...

- combine graduate education and applied research & development with engineering excellence and project experience,
- quest for smart & high hygienic factories, and
- condense time-to-market by Quality-by-Design."



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Activating knowledge, creating values.

We are Process Engineering Professionals.

"What we are doing is acting as a connector between molecular level and economic processes by providing

- process development & optimization,
- process design, engineering & validation, and
- process and knowledge based life cycle management solutions."



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Being in good company

- Process [.-ING] roots go back to Sulzer AG which was founded in 1834 by Sulzer brothers as innovators of industrial building services.
- Inspired by „Course X“ idea (MIT Department of ChemE & MIT Sloan) [.-ING] collaborates with Hochschule Fresenius School of Chemistry, Biology & Pharmacy, founded 1848 by Carl Remigius Fresenius.

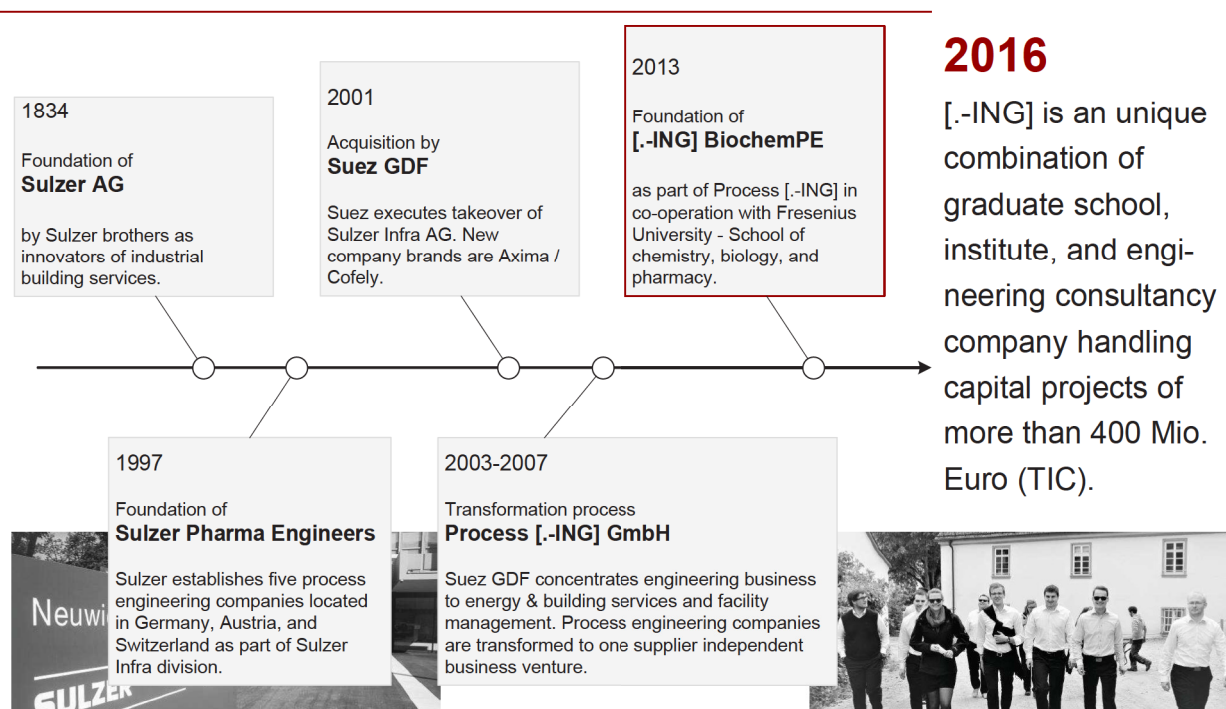


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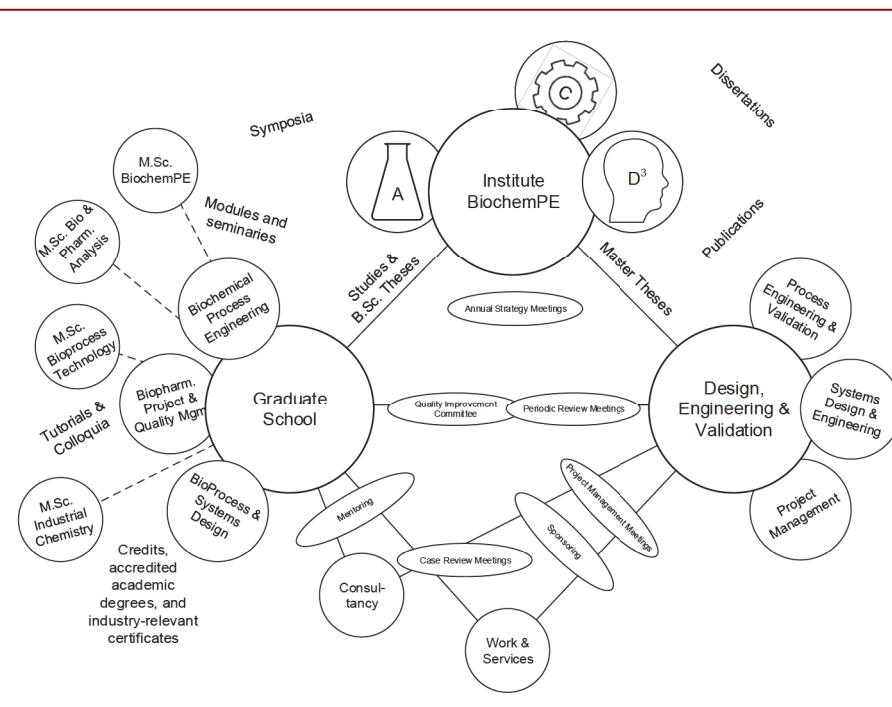
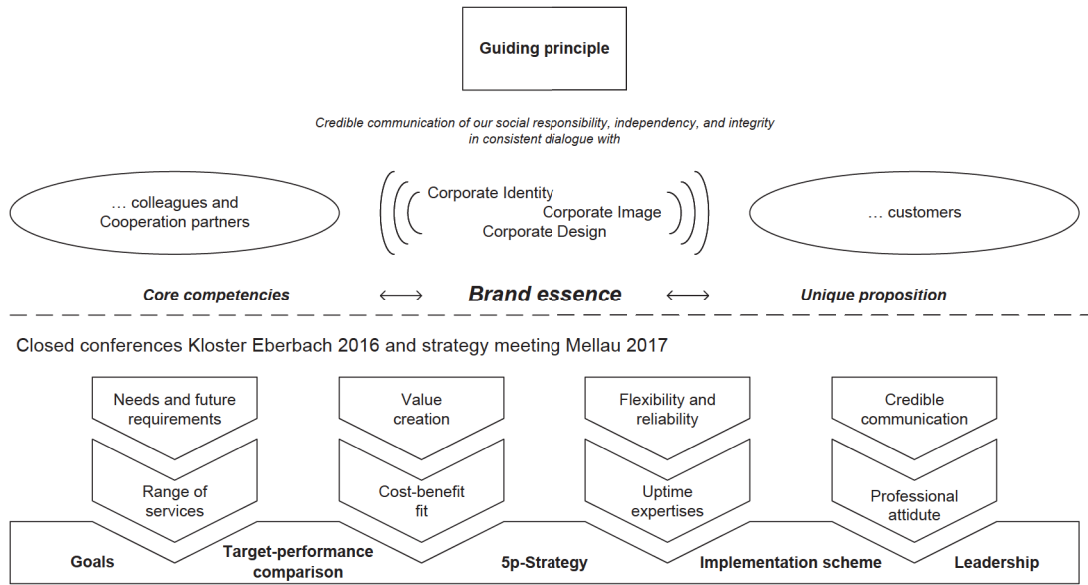
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Pole position 2017



**One
guiding
principle,
three
multipliers**

Process [-ING] GmbH
Design, Engineering & Validation
[-ING] BiochemPE
Graduate School & Institute of
Biochemical Process Engineering
Gaishorn [-ING] GmbH
Ingenious Equity Company

Process [-ING]'s company expertise

Consultancy & Project Management Design, Engineering & Validation for Pharmaceutical Process Industry

R&D and large scale plants for biopharmaceuticals, vaccines, and facilities for manufacturing of sterile dosage forms.

- Upstream, bioseparation, and downstream processing,
- cleaning and sterilization, sterile drug formulation, and aseptic fill & finish incl. lyophilization,
- inspection, labeling & packaging, and pharma logistics,
- clean media utilities,
- HVAC and clean room technology,
- Automation & Control.

Process [-ING] is a leading German engineering & consultancy provider with 20 years of experience based on more than 150 industrial projects handling customer's volume of investments of much more than 400 Million Euro (TIC).

- Quality, technology, and HR consultancy,
- project management,
- design, engineering and validation services

as service arrangements and work & service contracts up until general planning responsibility (EPCMV).

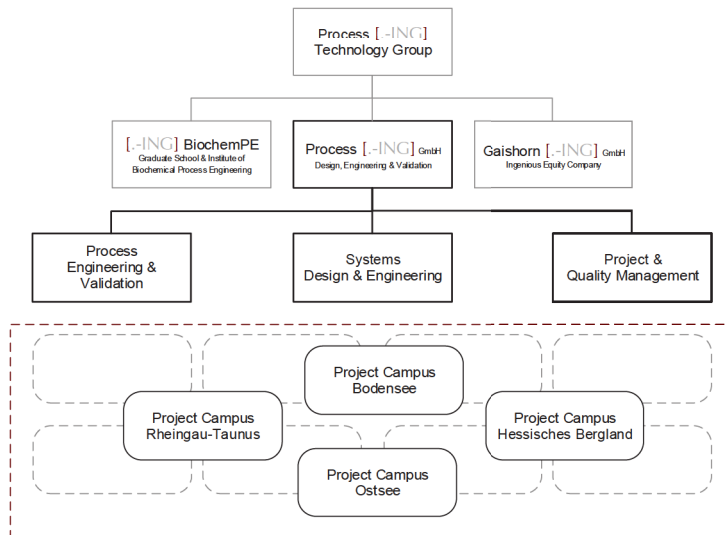
Core competencies: Professional process engineering services with a high degree of engineering education and operation of a network of more than 100 specialists.



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Group overview



[-ING] Technology is an unselfish partnership of experienced and independent consulting engineers subdivided in three corporate bodies.

Process [-ING]'s purpose is the development of knowledge and expertises providing professional engineering and consultancy services to pharmaceutical process industry.

Process [-ING]'s activities are supported by

[-ING] BiochemPE, a non-profit organization funded by experienced and independent consulting engineers, dedicated to promote education of technology experts and to enable research in biochemical process engineering, and

Gaihorn [-ING], a private equity company supporting business ideas, business development, and commercial exploitation.

Illustration: Overall structure [-ING] Technology.

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Expertise in Process Engineering & Validation

Sterile Process Engineering & Validation Biotechnology & Bioanalytical Services

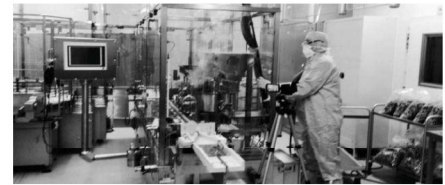
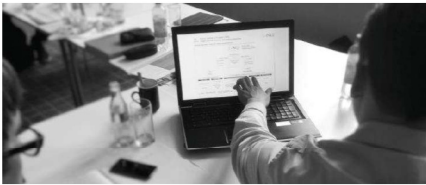
for small, medium, and large scale microorganism fermentation and cell culture. Manufacturing and packaging processes for production of small volume parenterals.

- Fermentation, separation, and downstream processing,
- in-place cleaning & sterilization (CIP / SIP / DIP),
- one to multi chamber washing equipment and autoclaves,
- weighing & compounding equipment for preparation of nutrients, buffers, and sterile drug formulations,
- machinery for fill & finish, inspection, and packaging for the production of small volume parenterals,
- in-process and QC equipment and devices.

[-ING] is set up to provide the complete range of life cycle services based on current EU- and FDA GMP considering latest inspectoral recommendations.

- Process engineering services,
- qualification planning for new and renovated facilities,
- proven and trained customizable set of test protocols DQ, IQ, OQ, and PQ,
- validation of sterilization / depyrogenization processes incl. heat distribution, microbiological / endotoxine starts,
- process and cleaning validation incl. laboratory work bench.

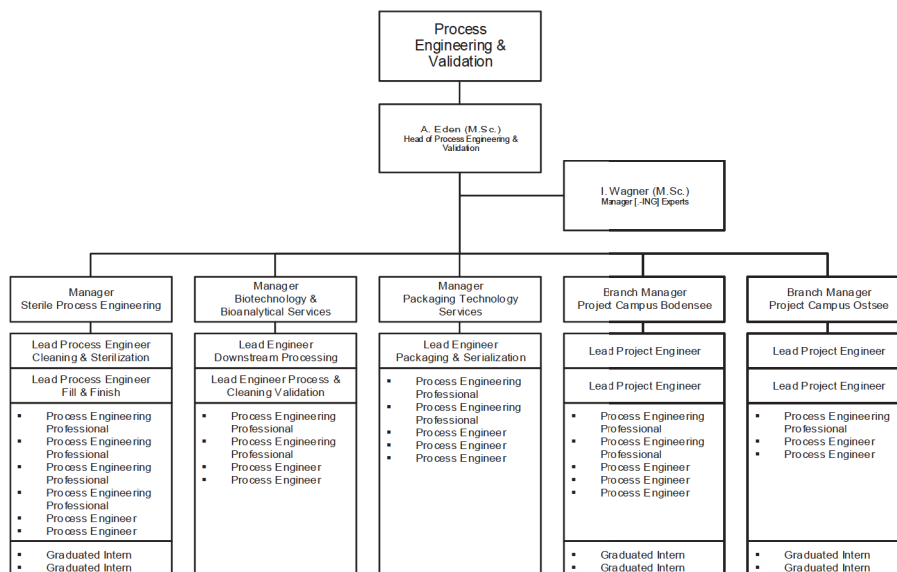
Closely connected with our fellow disciplines, two branches and a network of more than 100 specialists, [-ING] is able to support customer's projects effectively by using state of the art QbD methods and risk based approach experience.



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Process Engineering & Validation operational set-up



[-ING] operational set-up in process engineering and validation is subdivided in three specialist groups and two branch offices.

Illustration: Organizational structure Process [-ING] GmbH / Department of Process Engineering & Validation.

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Expertise in Systems Design & Engineering

Process Development, Optimization, and Design Engineering life cycle services

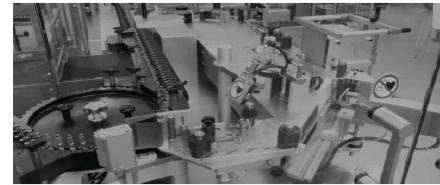
for industrial production plants,
 high hygienic process systems and building services for
 manufacturing facilities and pharma distribution.

- Recipe-controlled process systems equipped with in-place cleaning, sanitization & sterilization (CIP / SIP / DIP),
- clean media utilities purified water, water for injections, clean steam, clean compressed air,
- generation units, storage & distribution systems,
- HVAC systems and clean room technology,
- PLC, SCADA and monitoring systems.

[-ING] is specialized in design and engineering using an advanced body of knowledge in order to establish a reliable proof of concept corresponded with EU-/ FDA-GMP combined with DIN-EN standards in process engineering & building services.

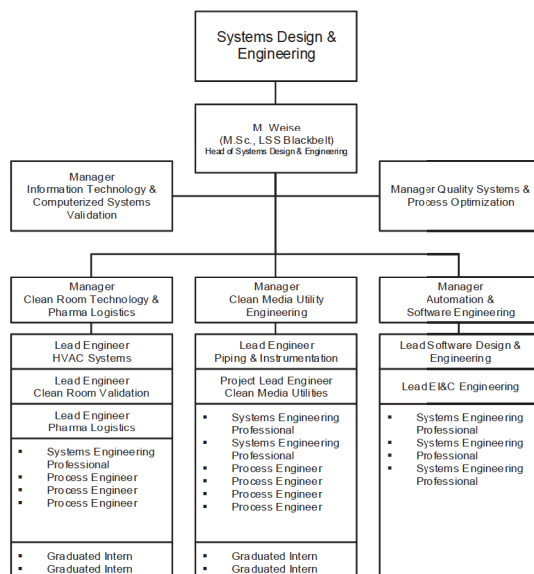
- Conceptual design and extended basic engineering,
- proven and trained customizable set of test protocols dedicated to HVAC qualification and clean room validation,
- process optimization services by using effective and efficient methods and tools of total quality and lean management six sigma.

Closely connected with our fellow disciplines, [-ING] is able to provide specialized engineering work and services for new facilities and renovation and remediation.



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Systems Design & Engineering operational set-up



[-ING]'s operational set-up in systems design & engineering is subdivided in three specialist groups.

Illustration: Organizational structure Process [-ING] GmbH / Department of Systems Design & Engineering.

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Expertise in Project & Quality Management

**Project & Quality Management Consultancy
 Project Engineering Services and
 Work & Service Contracts up until EPCMV responsibility**

Planning and realization of industrial capital projects for new facilities or upgrade, renovation and remediation projects in EU-GMP and FDA regulated environment.

- Project conception and initiation,
- project definition and planning,
- project engineering, procurement, construction management, and validation,
- project performance and acceptance control,
- project delivery and closure.

[-ING] enhances customer's projects with an effective application of PM and QM body of knowledge in accordance with DIN-ISO standards and recommendations of U.S. Project Management Institute in order to meet quality, cost & schedule requirements directed and controlled from start to finish.

- Project management and execution modelling,
- plant and project structure planning ,
- procurement and assignment planning, scheduling and simulation,
- cost-performance acquisition and project analysis,
- deviation & claim management and change control.

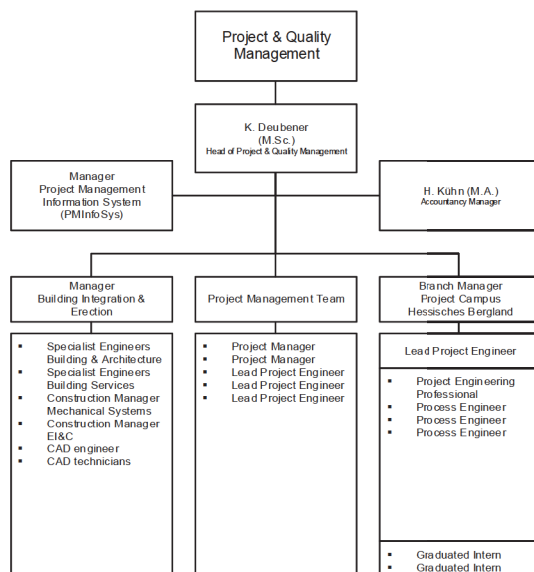
Closely connected with our fellow disciplines, [-ING] is able to consolidate GMP, budget and schedule requirements by efficient and effective integration of in-house specialists, project engineers and project management.



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Project & Quality Management operational set-up



[-ING]'s operational set-up in project & quality management is subdivided into two specialized groups and a branch office.

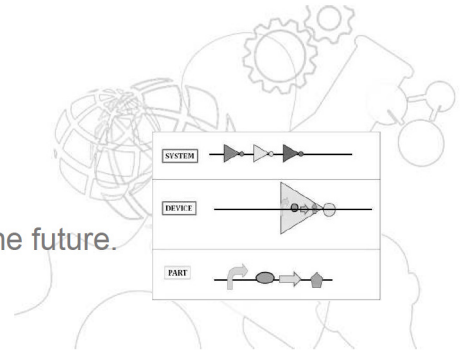
Illustration: Organizational structure Process [-ING] GmbH / Department of Project & Quality Management.

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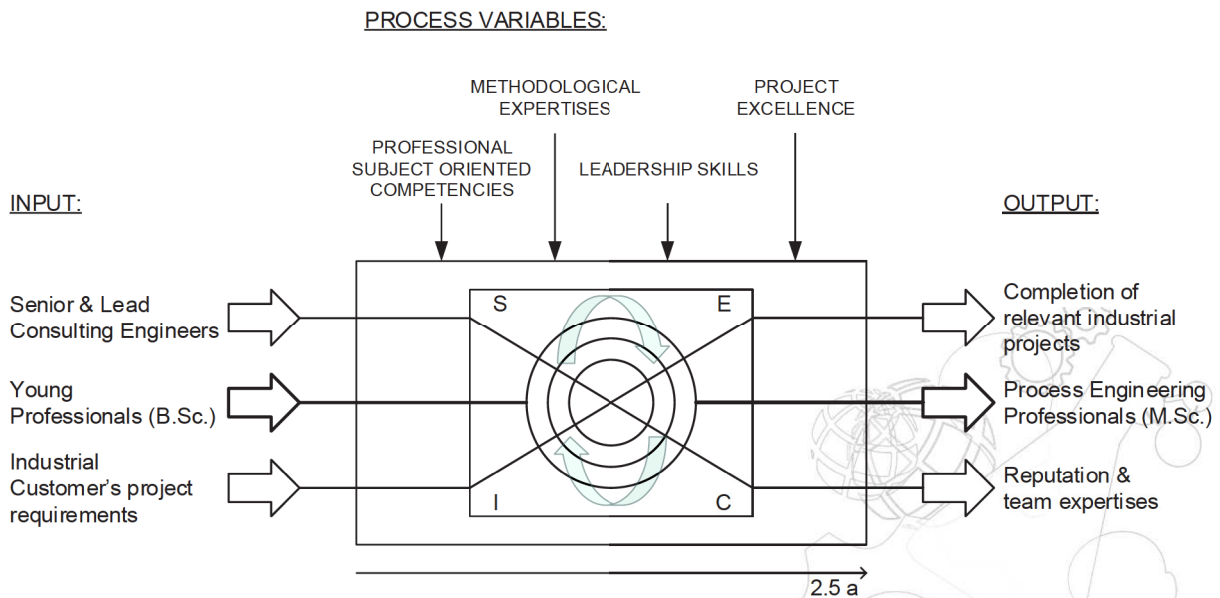
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BiochemPE matters

- In the 21th century quality of life is closely connected with the challenge to move nowadays medicine from a reactive to a proactive discipline.
- BiochemPE matters in order to combine chances of **Synthetic Biology** and the possibilities of **Internet of things and services** to enable benefits of a **“P4” Medicine** what means a predictive, personalized, preventive and participator benefit for society.
- **Pharmaceutical Process Industry 4.0** resulting from a fourth industrial and a second pharmacological revolution will lead to a major contribution to „P4“ medicine in the future.



Course X idea represented by black box model



Course X idea: Body of knowledge and proof of concept

The motto „Mens et Manus“ (mind and hand) reflects [-ING]'s ideal of synergy between knowledge and practice

Subject oriented competencies, methodological expertises, professional leadership skills, and industrial practice.

- M.Sc. Executive Initiative and post graduated program,
- job attendant M.Sc. Degrees in Industrial Chemistry, Bio & Pharmaceutical Analysis, Pharmaceutical Biotechnology, and Biochemical Process Engineering in cooperation with Hochschule Fresenius – School of Chemistry, Biology & Pharmacy,
- mentoring and tutorials & revision courses in blended learning approach,
- advanced certificate system.

Course X is an artful blend of competencies, skills, and abilities carefully designed in partial fulfillment with

- German Council of Science and Humanities,
- amended law of „Ingenieurgesetz“ reflecting the current position papers of VDI, the national chambers of engineers, and associations of consulting engineers,
- current EU and FDA GMP regulatory, ICH Guidelines, and ZLG recommendations as written in Aide Memoires,
- DIN-EN standards applicable in process engineering, building services, and project & quality management,
- grade Project Management Professional (U.S. Project Management Institute) and Lean management six sigma blackbelt,
- qualification profile „Qualified person“ with regard to EU directive (2001/83/EG) under consideration of VFA position papers.

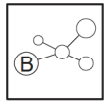


BIOCHEMICAL PROCESS ENGINEERING (M.Sc.)					
Course design:	Semester 1:	Semester 2:	Semester 3:	Semester 4:	Semester 5:
Subject oriented competencies	MOD 1 INTRODUCTION TO PHARMACEUTICAL PROCESS INDUSTRY	MOD 5 MANUFACTURING OF STERILE DOSAGE FORMS	MOD 8 BIOPROCESSING I UPSTREAM PROCESSING	MOD 13 BIOPROCESSING II BIOSEPARATION & DOWNSTREAM PROCESSING	MASTER THESIS contributing to research, development, and competence clusters (A to U) as follows: A:= Pcess development & intensification B:= Accelerated process & plant design C:= Integrated engineering, procurement, construction management & validation D:= Knowledge based life cycle management expert systems
	MOD 2 STERILE PROCESS ENGINEERING	MOD 9 PROCESS AUTOMATION	MOD 14 BIOANALYSIS		
Methodological expertises	GOOD ENGINEERING & MANUFACTURING PRACTICE: DESIGN, ERECTION, AND OPERATION OF PROCESS PLANTS			MOD 15 IN-PROCESS & QUALITY CONTROL METHODS	
	MOD 3 PHARM. PROCESS VALIDATION I EQUIPMENT QUALIFICATION	MOD 6 PHARM. PROCESS VALIDATION II REGULATORY BASIS & ADVANCED VALIDATION METHODS	MOD 11 PROCESS OPTIMIZATION	MOD 16 PROCESS DEVELOPMENT & INTENSIFICATION	
Professional leadership skills	MOD 4 PROJECT MANAGEMENT I+II	MOD 7 GERMAN LAW OF OBLIGATIONS & ACCOUNTING	MOD 12 PROJECT MANAGEMENT III	MOD 17 KNOWLEDGE MANAGEMENT	
Revision courses, tutorials, and advanced studies	Kinetics of thermodynamic and fluid mechanical processes Biotechnology: General survey and fermentation kinetics	Pharmacodynamics and -kinetics Biochemistry: nucleic and amino acids, peptides and proteins, monoclonal antibodies	Mathematics and modeling of transport phenomena Total Quality Management (TQM) toolbox, Quality-by-Design (QbD) & lean management six sigma approach	Introduction & survey Genetic & metabolic engineering	Scientific positioning & study design

Institute's research, development, and competence clusters



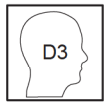
Product novation
Generic innovation
Process intensification



Accelerated
product development &
process design

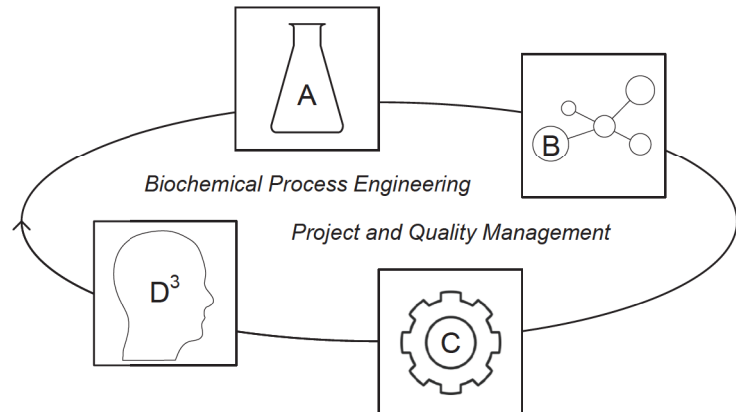


Integrated
engineering, procurement,
construction mgmt. & validation



Knowledge based
Pqm Life Cycle Management
Expert System

CONDENSED TIME-TO-MARKET AND QUALITY-BY-DESIGN APPROACH



Quality and technology improvement

- From 01 March 2017 managing partner Dipl.-Ing. Ruth Wohlfahrt will be responsible for technical management in a cross-project approach.
- In that respect she will also act as managing director of Process [.-ING] GmbH paying special attention to continuous improvement of quality, efficiency, and effectivity.

Graduate school & institute

- In future managing partner Dipl.-Ing. Geis will enforce design, marketing, and accreditation of M.Sc. Course BiochemPE.
- Against this background a project is founded by [.-ING] and Fresenius. Marketing milestone is 01 June 2017 / Accreditation milestone 30 September 2017.
- Parallel business development of certificate system will start focusing on industry relevant advanced training.

- Symposium Biochemical Process Engineering WS 2016/17 will take place in Kloster Eberbach / Rheingau (Germany) on 20 April 2017. Symposium distributes to (i) synthetic biology, (ii) today's working world and process industry in the future, (iii) scientific plenary- and poster presentations based on theses WS 2016/17, (iv) congratulations of M.Sc. graduates.
- **Corporate and departments identity and image**
 - Works meetings with colleagues for discussions and feedback loops.
 - Discussing career opportunities for graduates and participants of M.Sc. Executive Initiative.
 - Meetings with customer's and co-operation partner's key persons.

- **Development and organizational projects**
 - Defining department's service distribution to company's structural and workflow organization.
 - Planning and realization of corporate and campus design incl. interior, workshop equipments and IT improvement.
 - Planning and introduction of PMInfoSys in combination with improvement of project management and accounting knowledge, methods, and techniques.
 - Planning and introduction of knowledge management system bringing together (i) SECI, (ii) expertises, (iii) documentation structure model with its lessons learned and best practice typicals, templates, and standards, (iv) citation and eBib system, as well as (v) communication tools.
 - Realization and launch of Web-Revision under consideration of platform interaction described above.