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Lunch & Learn Events at ILMAC Forum

ILMAC 2016 is being staged under the motto 'ILMAC 4.0'. During lunch times, the ILMAC Forum will be looking at this topic with three different thematic key aspects and provides a platform for recognized experts from industry and academia.

The ILMAC Forum events are open to all visitors. No registration is needed. The Lunch&Learn sessions and discussions will be held in English.

You will also find the current Forum programme online in the event calendar on the ILMAC website. All the events are included in the admission to ILMAC.

Wed, September 21, 2016

«Automatization and Huge Data Handling in Analytical Sciences»
Organized by the SCS Division of Analytical Sciences (DAS)
Contact: Prof. Dr. Götz Schlotterbeck, FHNW

11.00 ***Standardization: The Way to the Next Generation Lab***
Dr. Daniel Juchli, Chief Technical Officer (CTO) SiLA Consortium, Basel
11.25 ***The ghost in the machine – The intelligent spectrometer***
Dr. Till Kühn, Bruker BioSpin AG
11.50 ***Innovative sample management and integration into fully automated walk-up analytics***
Dr. Ingo Muckenschnabel, Novartis Pharma AG
12.15 ***Towards a fully automated workflow in NMR&MS analytics from sample preparation to report. Have we broken down all barriers?***
Dr. Josef Schneider, F. Hoffmann-La Roche AG
12.40 ***Revolution in the lab? From handwritten labels to lab 4.0***
Dr. Günter Böhm, CTC Analytics
13.05 Q&A and Round table discussion
13.30 Lunch and Networking event
14.00 End of the session

Thu, September 22, 2016

«Automatization in the Laboratory Environment»
Organized by i-net and Swiss Biotech Association (SBA)
Contact: Ralf Dümpelmann, BaselArea, i-net innovation

11.00 ***From pipetting slave to IT-wizard***
Prof. Sven Panke, Dept. of Biosystems Science and Engineering, ETH Zurich
11.25 ***Lab automation, the weak little stepsister of the industrial automation***
Dr. Erwin Althof, Scientific Technical Leader, Novartis Pharma AG
11.50 ***Scalable production of organotypic 3D microtissues for safety and efficacy testing***
Dr. David Fluri, Senior Scientist, InSphero AG
12.15 ***Gamification of Research & Development***
Dr. Rolf Gueller, Founder and CEO, Chemspeed Technologies AG
12.40 ***The Next-Generation Health Data Integration Platform***
Dean Corkovic, BCPlatforms
13.05 Q&A and Round table discussion
13.30 Lunch and Networking event
14.00 End of session

Fri, September 23, 2016

«Industry 4.0 in Chemical Engineering»
Organized by SCS DIAC, SGVC and SCV
Contact: Andreas Schreiner, Novartis PharmOps Switzerland

11.00 ***What's behind Industry 4.0?***
Dr. Peter Bürgin, ControlTech Engineering AG
11.25 ***From Lab Data to 'Big Data' – closing the gap between R&D and Production***
Dr. Tobias Merz, Lonza AG
11.50 ***Manufacturing IT & Industry 4.0: success factors for projects – practical examples***
Dr. Stephan Gentner, DSM Nutritional Products GmbH
12.15 ***Process industry 4.0 in manufacturing engineering research***
Dipl.-Phys. Mario Bott, Fraunhofer-Institut für Produktionstechnik und Automatisierung IPA, Stuttgart
12.40 ***Industry 4.0 – Future of Process Technology in the Chemical / Pharmaceutical Industry***
Dr. Andreas Schreiner, Novartis PharmOps Switzerland
13.05 Q&A and Round table discussion
13.30 Lunch and Networking event
14.00 End of session

Dr. Max Lüthi Awards 2015 and 2016

After the Friday Lunch&Learn Session the ceremonies of the Dr. Max Lüthi Awards 2015 and 2016 will take place, followed by the lectures of the two awardees.

The Max Lüthi Award 2015 is given to **Yvan Mongbanziama** for his Bachelor thesis describing the synthesis and characterization of a new enantiomerically pure verdazyl radical derived from pinene.

Lecture: Fr, 23.09.16, 14.10h, ILMAC Forum

The Swiss Chemical Society awards the Dr. Max Lüthi Prize 2016 to **Flavio Gall**, ZHAW Wädenswil, for his Bachelor Diploma Studies on the design and synthesis of cyclic metalloprotease inhibitors.

Lecture: Fr, 23.09.16, 14.30h, ILMAC Forum

ILMAC Forum «Automatization and Huge Data Handling in Analytical Sciences»

Wed, 21.09.2016, 11.00
Standardization: The Way to the Next Generation Lab

Dr. Daniel Juchli
Head Lab & Research IT at wega Informatik AG, Basel, daniel.juchli@wega-it.com and Chief Technical Officer (CTO) SiLA Consortium, daniel.juchli@sila-standard.org

Companies dream of establishing the Next Generation Lab, using internal resources in a more efficient way while at the same time enhancing the quality of the lab output. One way to plan, execute and live this dream is to focus on industrial standards during the development, implementation and operation phases.

How can industrial standards and concepts from Industry 4.0 help companies to efficiently implement and operate systems like LIMS, ELN or LES in Next Generation Labs? Can modern labs profit from the Internet of Things and the Internet of Services? What are the advantages and where are limitations when evaluating the Lab of the Future?

Wed, 21.09.2016, 11.25

The ghost in the machine – The intelligent spectrometer

Dr. Till Kühn
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NMR is a very powerful technology to address many analytical questions. However, the power of the method is reflected in its complexity and the wealth of choices of different experiments one can perform. The selection of which experiments with what set of parameters to apply for a certain question is a very complex task and requires a high degree of expertise – especially since quite often one needs to decide on the selection of follow-up experiments for a given problem only after the interpretation of a 'scout' experiments.

Here we highlight the path of a very typical NMR application: structure verification as often applied for chemical synthesis control. Here, one is confronted with the problem that a simple 1D proton spectrum may not yield the required information. In many cases additional, and often more time consuming, experiments are used or simply solvent suppression *etc*. is required. Therefore, very often in labs today, either only the 1D 1H experiments are run – which are in many cases insufficient - or by default a whole suite of experiments is run – whether useful or not. Here we present first results of an innovative, new solution that enables automatic on-the-fly decision making on the NMR spectrometer to suggest the ideal combination of experiments, taking into account the time available and confidence required and we present a statistical evaluation of the automatically generated results.

Therefore, the user will not have to tell the system exactly which experiments to run with which exact parameters and in what order. Instead, the user simply tells the system which problem to solve and how much time the machine should spend on this. The instrument will automatically determine the best way to come up with the best solution in the given time.

Wed, 21.09.2016, 11.50

Innovative sample management and integration into fully automated walk-up analytics

Dr. Ingo Muckenschnabel
Novartis Pharma AG, Basel, ingo.muckenschnabel@novartis.com

Key points:

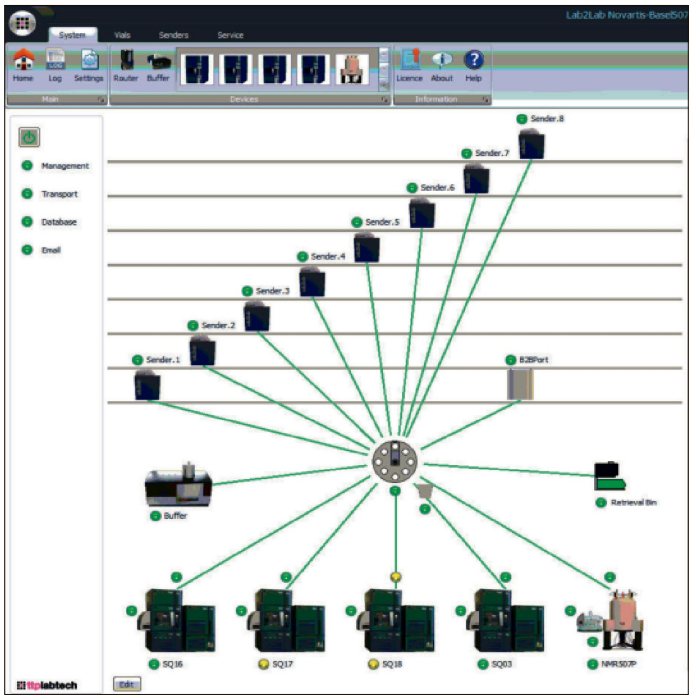
- Innovative sample logistics concept for automated transportation of vials within a building and between buildings
- Fully integrated with automated platform for open access analytical support
- Easy access for all associates to high-end analytical instrumentation
- Higher utilization of shared instruments
- Result integrity ensured by barcode sample tracking
- Faster result return to customer

Wed, 21.09.2016, 12.15

Towards a fully automated workflow in NMR&MS analytics from sample preparation to report. Have we broken down all barriers?

Dr. Josef Schneider
F. Hoffmann-La Roche AG, Basel

NMR and MS analytics play an essential role in pharmaceutical industry. As there is a high need to bring new medicines faster to the market the work processes also in NMR and MS analytics must be optimized to generate the results faster with existing or reduced resources. Automation is key to enhance the efficiency. The talk will show the established level of automation in the NMR&MS analytics at Roche Basel for automated sample preparation, paperless interpretation and generation of result reports. In spite of a very high automation level some processes like the reliable and applicable automated structure verification are not fully automated yet. The hurdles to overcome this challenges will also be discussed.



Wed, 21.09.2016, 12.40

Revolution in the lab? From handwritten labels to lab 4.0

Dr. Günter Böhm
CTC Analytics, Zwingen, gboehm@ctc.ch

Today the levels of lab automation vary greatly, sometimes even within the same lab. Often high end projects are presented, but the reality in many labs is much more mundane. The presentation looks at these different levels and the challenges and opportunities ahead on the road to lab 4.0.

ILMAC Forum «Automatization in the Laboratory Environment»

Thu, 22.09.2016, 11:00

From pipetting slave to IT wizzard

Daniel Gerngross, Sven Panke (photo)
Department of Biosystems Science and Engineering, ETH Zurich, Mattenstrasse 26, CH-4058 Basel, sven.panke@bsse.ethz.ch

The classic biotechnology laboratory is undergoing dramatic change, at the end of which it will be difficult to recognize. Two developments are central in this context: First, the advent of large scale chemical DNA synthesis, and second, the introduction of miniaturization into experimentation. DNA synthesis allows outsourcing of one of the most time-demanding lab activities, the construction of specific DNA fragments, in a cost- and time-efficient manner, and the time that is gained can be re-invested for different things,

such as computer aided experimental planning. Miniaturization and the corresponding parallelization of lab experiments enables the increase of information density, or the information harnessed per experiment. As one of the results of these developments, the future work in a biotechnology lab will much more rely on computational support, with the corresponding effects on the training of future biotechnologists.

Template-free DNA synthesis

The construction of DNA fragments with pre-determined sequences is one of the most basic lab activities in a modern biotechnology laboratory. Whether it is to convince a bacterium to synthesize a bulk chemical or to add numbers,[1] or a mammalian cell to synthesize at a specific point in time an enzyme required for the release of sperm cells from a cellulose bead for artificial insemination,[2] or to construct genetic circuits that can integrate multiple effects of small molecules in large screens for new therapeutic ingredients[3] – always the first activity is the construction of a DNA fragment of a specific sequence of increasing length, nowadays up to 10^6 base pairs.[4] Classic DNA-production processes such as the template-dependent polymerase chain reaction allow only the introduction of a few sequence changes during the copying of natural DNA-templates. However, chemical, template independent DNA synthesis allows the (nearly) free programming of a DNA sequence according to the specifications required by the project, including the consideration of genetic standards that guarantee compatibility between different design projects.[5]

Chemical DNA synthesis can be obtained nowadays at a price around 0.2 €/bp, depending on the required quality, from a large number of providers. At this price level, it becomes easily possible to outsource the construction of up to 30 kbp of DNA fragments and more per researcher and year. As a consequence, a large fraction of the everyday work of a standard PhD student in molecular or cellular engineering is about to vanish for good.

Miniaturization and parallelization

Unfortunately, our knowledge on how to write (how to encode information as DNA) does not keep pace with our ability to write as such (our capacity of DNA synthesis). There are still many gaps in our understanding of how we can program the instruction for a specific cellular process. Of course we know in principle how to encode protein sequences, promoters, terminators, *etc.* – but when we need to master the transition from qualitative understanding to quantitative design, we realize rapidly that we cannot deliver DNA molecules that produce precisely the desired effect according to specifications. And often enough we have to admit, that we do not really understand why a DNA construct does not work in the anticipated fashion. As a consequence, our ability to produce DNA chemically at large scale is often used not for the synthesis of one specific fragment, but rather for the construction of a library of fragments with relatively little variation, in the hope that within this variability we can find the molecule encoding the desired properties. Of course this implies that the different molecules all (or at least most of them) need to be investigated. This chimes together with a second fundamental transition in the modern experimental biology lab, which it the transition to miniaturized experiments. Miniaturization means also reduced experimental volumes and often the possibility to realize a specific experimental setup with a high degree of multiplicity on a small chip, so that parallelization is the highly desirable other side of miniaturization. As a consequence, we move from laborious Erlenmeyer-flasks *via* expensive microtiter-plate and pipetting robots to nanoliter sized experimental setups that allow the nearly concomitant treatment of several thousands of experiments and more, often integrating several complex experimental steps on one chip. As a result, more and more rather complex protocols can nowadays be realized on (sometimes fully automated, see next-generation sequencing) technological platforms. Clearly, our ability to read out the different properties of DNA-molecule libraries matches the increasing size of these libraries.

Lab 2.0

Chemical DNA-synthesis and miniaturization and parallelization of experimental protocols advance into more and more areas and revolutionize what is considered a standard activity in a biotechnology laboratory. Instead of progressing at a sturdy rate of one plasmid per week, complex sets of information of 30 kbp's worth need to be encoded, with combinatorial variations in certain segments to obtain optimal performance in a microfluidic experimental setup. The competences for this new mode of operation need to be acquired during academic training, and it will change the typical set of activities that need to be studied. Clearly, the complexity of future projects, in terms of information but also in terms of experimentation, will increase, and the only way to deal with this in the lab is by recruiting computational support into the biological and experimental design process. No mature IT-solutions exist yet, but the general direction is clear: we need computational platforms that support the practical implementation of complex genetic designs and, wherever possible, integrate the increasing fundamental and theoretical knowledge that we

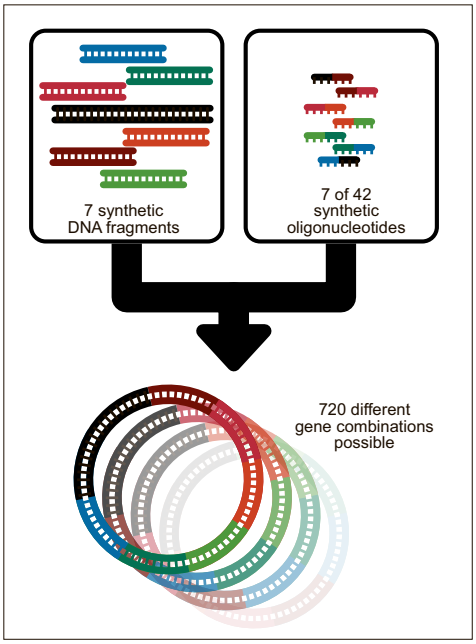


Fig. 1. Novel gene assembly techniques allow the construction of libraries with large diversity using only few starting DNA fragments. In this example, seven synthetic gene fragments are assembled into all 720 possible permutations with respect to gene sequence using guiding guide oligonucleotides.[6]

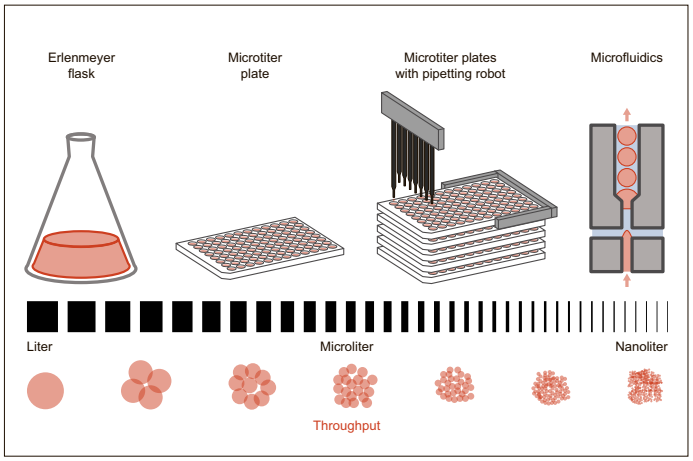


Fig. 2. Scaling down volumes of an experimental setup allows increasing the throughput of simultaneous experiments. With technologies like liquid handling robots and microfluidic chips smaller and smaller volumes can be handled and corresponding experiments evaluated.

accumulate for biosystems design to at least check for design plausibility.

Acknowledgment

This work is supported by the Swiss National Science Foundation as part of the NCCR Molecular Systems Engineering

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Thu, 22.09.2016, 11.25

Lab automation, the weak little stepsister of the industrial automation

Dr. Erwin Althof
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As a patient-focused healthcare company, Novartis discovers and develops innovative products to cure diseases and to enhance the quality of life. The Novartis Institutes for BioMedical Research, NIBR, is Novartis' research arm.

Lab automation is an essential part to provide key capabilities in NIBR. However, most scientists seem to be skeptical with regard to automation in the lab environments. The presentation will provide answers about particular requirements and what automation-specialist at Novartis do to provide adapted automation solutions for research.

Compound screening

The ultimate goal of screening is to find a chemical compound that modulates disease relevant targets – often a protein that plays a critical role in that disease. Compounds that manipulate the target in a way that might cure a disease, or mitigate its effects, are called leads.

The result of a screening campaign is a set of compounds called a hit list. A hit list can include thousands of compounds that appear to show the desired effect on the target.

In the effort to find new relevant structures or leads, large collections of molecule libraries containing compounds from former research projects, chemistry or natural products are screened with automated high throughput screening systems (HTS).

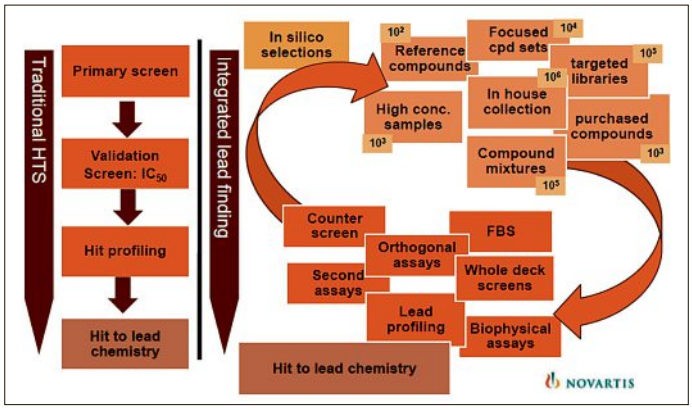
HTS was developed in the 1980s. Initially, the focus was screening as many compounds as possible in the shortest time using large monolith systems running linear processes.

Screening infrastructure

Targets researched these days typically require more complex assays. So the focus has shifted to carrying out the best screen for the target, not necessarily the fastest.

The high throughput concept was extended to allow more experimental design and iterative approaches.

Novartis leads the pharma industry in the area of high-content screening and is one of the few pharma companies using image-based technologies in primary screening.



Modern screening systems consist of several interacting components like process control systems, logistics, data management systems, data evaluation systems and more.

What do automation specialists at Novartis do to provide state of the art, adapted automation solutions and concepts?

In principle we can face two approaches:
1. Application specific turn-key solutions.
2. Highly flexible all-rounders

Visualization of processes and business analyses seems to be very challenging in the lab automation and research environment. Processes have in many cases a short life span and need to be adapted to the fast changing requirement in research. Screening systems incorporate a sinfonia of synchronous and asynchronous processes and tasks. With the concept of reusable functionality related modules or blocks we are able to generate flexible automation system in a reasonable timeframe.

Thu, 22.09.2016, 11.50

Scalable production of organotypic 3D microtissues for safety and efficacy testing

David Fluri and Jens M. Kelm
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In vitro efficacy and safety testing in the pharmaceutical industry still strongly depends on 2D culture systems. The advantages of more complex 3D model systems, incorporating multiple cell types and mimicking organotypic tissue morphologies, have been demonstrated in recent years. The implementation of these technologies in routine testing schemes has proven difficult owing to the complexity of the

required production and culture systems. We developed a scalable production and assay platform for 3D microtissues which is compatible with standard liquid handling robotics and amenable to mid-throughput applications. A high degree of standardization and comparatively low production costs provide new possibilities to implement complex and more predictive 3D models in routine testing applications.

Cellular self-assembly: a scalable 3D microtissue production technology

Mammalian cells have always been known for manufacturing of biologicals. More recently, mammalian cells have gained increasing importance for use in regenerative medicine, cell-based assays and as a therapeutic tool themselves. Hence bio-manufacturing technologies have gained another discipline, scalable production and processing of cells and tissues. In contrast to producing tissues for regenerative purposes, producing tissues for drug discovery and development always requires significantly more tissues per experimental run. Whereas in regenerative medicine only 3–5 tissue constructs per patient requiring a large number of cells are being produced, for drug discovery and development up to 100'000 smaller tissues could be needed in a standard format. Therefore, a careful balance between increasing biological complexity, production robustness/reproducibility, flexibility of the technology, standardization, and costs need to be considered in this setting.

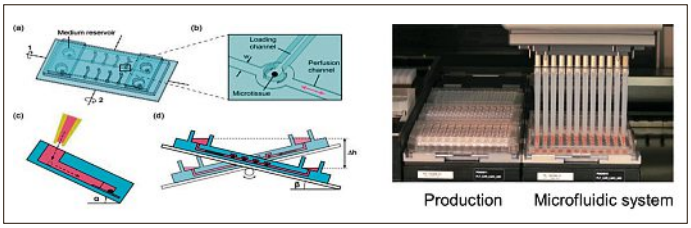

Fig. 1. Microtissue (MT) production by cellular self-assembly in a 96-well hanging drop platform (GravityPLUS™). The hanging drop technology permits production of various tissue types such as pancreatic islets, liver microtissues, PDX-derived tumor microtissues and microskin.

Prerequisite for the production of several hundred or thousand microtissues for an industry-scale testing run is to pre-qualify the cell source, including cell lines, PDX-derived or primary cells. Especially when working with primary or PDX sources, pre-qualification is essential to ensure high quality and reproducibility of the microtissues. The fewer cells required for the 3D model, the more data points that can be generated from a single cell batch, providing a sustainable cell source for a discovery and development project.

Production reproducibility is exemplified by 3D InSight™ human liver microtissues. intra-plate size variability is qualitatively shown in Fig. 2 as well as the assay variability of a 14-day repeat-dosing hepatotoxicity assay. IC50 values were calculated based on a 6-concentration dose-response curve from more than 20 compounds.

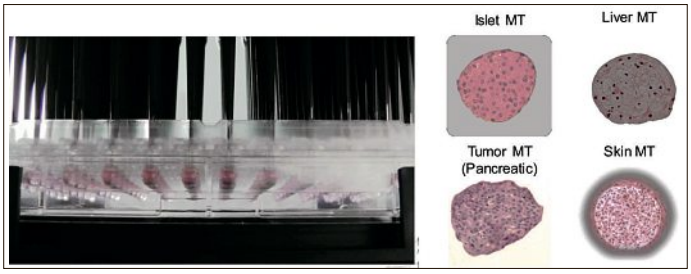

Fig. 2. Intra-plate reproducibility of microtissue production and resulting reproducibility of subsequent microtissue viability testing shown by IC50 values [µM] over different production runs and compounds.

Scalable microphysiological systems

Yet another level of complexity is added if a 3D tissue-based assay can link two or more different tissue types, *e.g.* liver and tumor. To maintain scalability of these assays, it is beneficial to uncouple the production and assay format. An automation-compatible system such as this has been developed together with the ETH Department of Biosystem and Science Engineering (BSSE). Microtissues are produced and qualified in hanging drop cultures, after which microtissues can be automatically transferred into the loading ports of the microfluidic device.

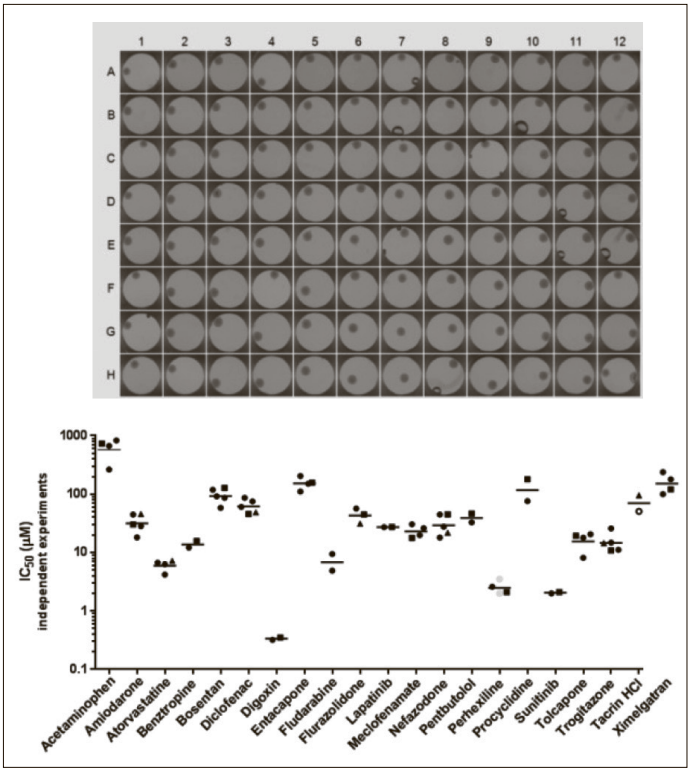

Fig. 3. Microtissue-based and tube-free body on a chip concept. Microtissues are produced off the chip and loaded into in the cultivation chambers on chip. A fluid flow is generated by tilting the chip enabling exchange of culture medium and cross-talk between the tissue types. The design concept is compatible with standard plate formats and automate liquid handling systems.

With the increased use of more complex *in vitro* models for drug testing, novel strategies are needed to ensure reproducible and robust production of 3D cell culture such as the 3D InSight™ platform. The more frequent use of increased biologically complex models is also an opportunity to further standardize *in vitro* models and assays to ensure intra-industry and inter-industry data comparability. Likewise, standardization is most likely a prerequisite for regulatory acceptance and increased efficiency of applying organotypic *in vitro* models in the future.

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Wed, 21.09.2016, 12.15
Gamification of Research & Development

Dr. Rolf Gueller
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Life science industry faces the increased demand for innovative medicines against various diseases. In this regard, time-to-market is the essence. Gamification of Research & Development represents a paradigm shift in life science research. It enables flexibility, diversity, standardization, and speed in the entire discovery process, *i.e.* sample management, reformatting, synthesis, purification, and biology testing based on an unprecedented automation concept.

For more information, please contact chemspeed@chemspeed.com.

Wed, 21.09.2016, 12:40
The Next-Generation Health Data Integration Platform

Dean Corkovic
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Population scale biobanks are crucial for future medicine. Whole genome data amounts are very large and require significant data processing and downstream data analysis. We will show you a case study where you can find a possible way to run a scalable and flexible platform with unique capacity handling massive calculations on demand and connect to your partners in the Health care ecosystem.

ILMAC Forum «Industry 4.0 in the Chemical Production»

Fri, 23.09.2016, 11.00
What's behind Industry 4.0?

Peter Bürgin
ControlTech Engineering AG, CH-4410 Liestal, Peter.Buergin@cte.ch

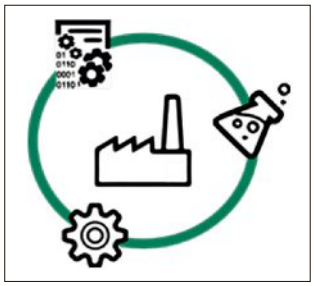
On the basis of a short flashback to the previous industrial revolutions there will be shown the mean aspects of Industry 4.0.

A real challenge of I4.0 is the increased requirement of communication over all levels. The result is a real chance in flexibility, but also a general risk in cyber security. I4.0 will be reality in future and will not only change the industrial way of life.

Fri, 23.09.2016, 11.25
From Lab Data to 'Big Data'– closing the gap between R&D and Production

Tobias Merz, Thomas Waniek, and Niklaus Künzle
Lonza AG, Rottentrasse 6, CH-3930 Visp, tobias.merz@lonza.com

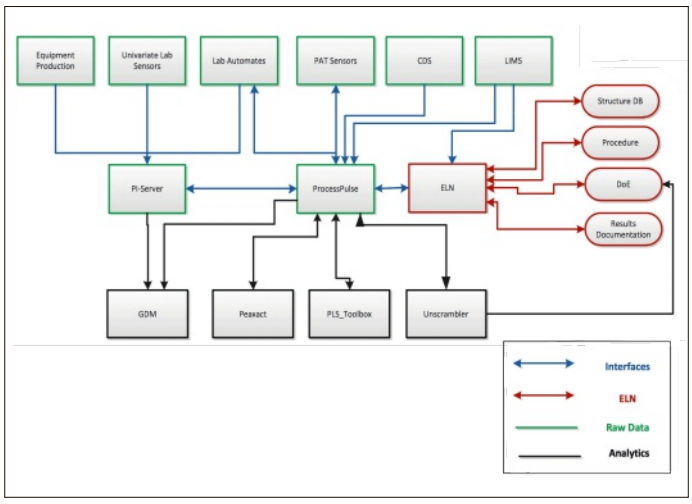
Increasing efficiency and effectiveness in product development is a major challenge in the chemical and pharmaceutical industries. Various initiatives like Lean Six Sigma, PAT or QbD have been established to speed up time-to-market and reduce R&D costs, but R&D costs for new chemical entities (NCE) are still growing. Typically, several projects teams are involved before the NCE is commercialized, but often the information flow and communication among teams is suboptimal. Reasons for this could be that the wrong information was recorded, raw data is missing, documents are available in different versions, links on a file drive are not working, the project name has changed during the development phase, people have changed positions, experience has not been documented, *etc.* All of these problems cause delays, such as the extra time needed to find missing information, and additional costs, perhaps because experiments need to be repeated.



To overcome these problems, the way of collecting, evaluating and interpreting data has to be changed. The initiative 'Industry 4.0' has one key driver: making smart decisions based on available data. Smart decisions from lab experiments require an 'information-rich' data set that contains physical and chemical properties – such as exothermic and kinetic information or the concentration of different species. With the right kind of online sensors, all information can be captured automatically. In addition to the information from online sensors, information from lab equipment such as temperature, stirring speed, dosing amount, *etc.* is also available.

To automate data collection, to merge the different data sources and evaluate the data in real-time an appropriate data management system was developed with the software company CAMO. The software 'Process PULSE' is able to record a broad spectrum of different file formats, connect to different instruments directly by SDK or OPC-UA interface, retrieve data from OSI-PI or Thermo LIMS, and save the data into a database. To evaluate the data, all models from Unscrambler, PLS_Toolbox or Peaxact can be applied. Furthermore, chemometrics 'on the fly' enables an insight into the process without any prior knowledge and allows the lab technician to decide on the appropriate time point to take a sample for reference measurements. Together with the experimental planning tool DesignExpert, Process PULSE and Unscrambler, a transparent workflow can be realized, starting from a systematic approach to perform experiments, followed by data recording and experiment documentation, and data evaluation in Unscrambler. The link from the raw data to project information is provided through the interface with an electronic lab notebook (ELN).

A schematic overview is displayed in following graph:



Fri, 23.09.2016, 11.50

Manufacturing IT & Industry 4.0: success factors for projects – practical examples

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With the classical approach in project management you will not be successful. A technical project normally has a clear goal, with a start and end. In Manufacturing IT & Industry 4.0 it is not clear how the world will look like when you are starting your project. Start, end and goal are often vague. In order to convince anyway the management, you need two things, which might be contrary: Agile project management and a strategy. Start small, create success stories and get bigger but always with standards and strong partners.

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Process industry 4.0 in manufacturing engineering research

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Modern life science laboratories and bio production facilities are highly complex data factories. The innovation cycles in life science R&D are currently outperforming the development of supplementary systems as automated infrastructure and data processing. Furthermore, the overall complexity and required process flexibility are overwhelming human being.

For mastering the upcoming challenges of small scale bio production – may be down to a lot size of 1 – a paradigm shift towards a holistic understanding of lab processes is crucial. Current laboratories apply a lot of advanced technologies. Nevertheless most devices, reactors and platforms are pretty dull if it comes to connectivity. The next evolutionary step is the seamless data and information flow within semi-automated environments. Each individual entity in the laboratory – such as devices, consumables, applications and the human being within the process – needs to be covered.

LabOS – an operating system for Pharma 4.0

Fraunhofer IPA has developed a concept for mass customization in the pharmaceutical process industry which is inspired by modern social media concepts, shared economy and a service orientated economy: LabOS. It combines properties of an operating system for laboratory devices with a strict service oriented approach. The concept gives a first understanding how cyber-physical systems may assist logistics, quality control, staff training and overall process control within laboratories and bio production.

LabOS will provide a standardized interface to address devices as a service and combine them to complex processes and applications. The same interface will give access for maintenance and device status monitoring, thus reducing risk and cost for repair and set-up time. LabOS will furthermore offer a LabStore interface to integrate third party applications and software. The LabStore allows to assemble lab specific process environments of sub-process modules and software components as schedulers or a company specific unified user interface. The services can all be controlled and monitored – centralized in a control suite or on the shopfloor with mobile devices.

Fig. 1. Vision of a cyber physical shopfloor.

The overall order management and scheduling is done by self-autonomous smart entities. The demand for personalized bio production thus translates in smart, decentralized bioreactor modules which are controlled via simple rule-sets instead of centralized complex control units. The overall documentation for regulatory affairs and process control accompanies the product as a digital shadow.

Furthermore cyber-physical assistant systems will find its way into laboratories and bio production. For managing the overall process complexity and match the requirements of regulations and documentation, visual support systems can be implemented. Augmented reality and gamification concepts thus can be applied to enhance training processes and guide through the process. Outstanding flexibility and risk management as a consequence.

Fig. 2. Visual support system at an assembly workstation.

LabOS – as an ecosystem

The digitalization of things and services will have a huge impact on current business models and value streams within a life science company. LabOS introduces a laboratory ecosystem interconnecting classical LIMS services, manufacturing execution systems and resource planning and controlling as SAP. The chal-

Fig. 3. Cyber physical systems will enhance human-machine interaction.

lenges of heterogenic software architectures are hereby covered by secure cloud technologies as "Virtual FortKnox" developed by Fraunhofer IPA.

The disruptive point about LabOS as an ecosystem is that the information flow does not stop at the boundaries of the laboratory. The ecosystem allows to integrate information of any kind as third party data of manufacturers or customers. The overall value stream – in particular with regard to the customer – gets transparent.

Managing complexity will become a decisive competitive factor and forms one of the core proficiencies of elite companies in pharma and bio production. LabOS thus might give access to next generation bio production – smart, personalized, sustainable!

[1] *http://www.ipa.fraunhofer.de/en/industrie-40_virtualfortknox.html*
[2] *http://www.ipa.fraunhofer.de/en/industrie-40_picasso.html*
[3] *http://www.wir-produzieren-zukunft.de/*

Wed, 21.09.2016, 12.40

Industry 4.0 – Future of Process Technology in the Chemical / Pharmaceutical Industry

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The first three industrial revolutions came about as a result of mechanization, electricity and IT. Now, the introduction of the 'Internet of Things and Services' into the manufacturing environment is ushering in a fourth industrial revolution, namely Industry 4.0. This facilitates fundamental improvements to the industrial processes involved in manufacturing, engineering, material usage and supply chain and life cycle management.

The talk will elaborate on the impact of Industry 4.0 on Process Technology in the Chemical / Pharmaceutical industry.