Management- und Technologieberatung AG

JSC AG

BA Technical Operations
Integrated Supply Chain Management for Biologics – iSCM
Version 1.1

Norbert Skubch, Dr. Ulrich Tulowitzki

2021

PUBLIC

Table of Contents

Accelerated Importance of Biologics and ATMPs (1)

The future in the innovative pharmaceutical industry belongs to biologics

- Biologics (NBE) are offered for entire patient groups (one-size fits all) or as specific medicine for single patients (tailored approach)
- Due to the size of biological molecules, the dominant dosage form is injection solution – therefore application technologies and devices play a critical role
- Personalized medicine is the trend – batch size one in production is the logical consequence, plants become smaller realized by scale-out instead of scale-up approaches
- Full availability and proper management of patient and process data are key to success of personalized medicine – at the best real-time data availability
- More and more innovations are coming from hospitals, universities and research institutes outside the industry – increased risk of failure has to be overcome by professional translation

ATMP - Advanced Therapy Medicinal Products, Advanced Therapeutics; Source: Internet

Accelerated Importance of Biologics and ATMPs (2)

- The asset is not anymore the pharmaceutical product, but technology platforms which can potentially be applied in several therapeutic areas
- Development and manufacturing are no longer separable, but must be more closely integrated – the safety of the drug is guaranteed by mastering and close monitoring of the manufacturing process
- New market participants in the supply chain arena positioning themselves as full service providers in outbound logistics [1]
- Professional partner management along the entire value chain [2] is becoming a condition sine qua none
- Due to the novelty of biologics, the general speed of innovation and the high degree of specialized know-how, there is a painful and ongoing shortage of qualified personnel thus intensifying the war for talent
- … and further reinforced by the age structure especially in the classic industrialized countries

(1) Amazon, Alibaba, UPS; Source: Internet, (2) research, development, production, logistics

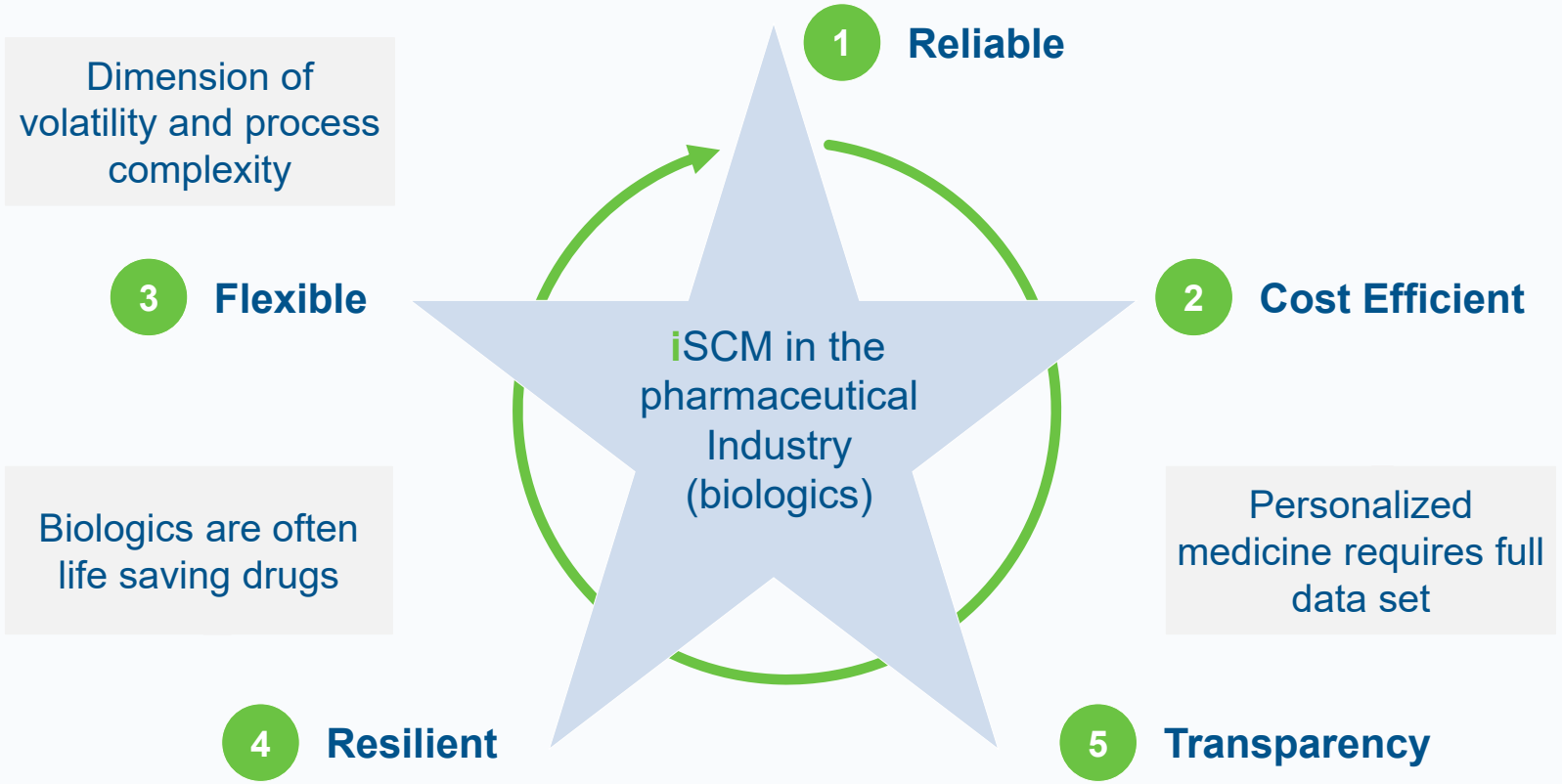
iSCM – Objectives (1)

Stable supply of medicine to patients is a mission critical task for Pharmacos – medicine is not a consumer product

(1) e.g. natural disaster man-made disaster legislation amendment, pandemic, civil disturbance, regulatory issue, chemical accident, infrastructure failure, EH&S issue, financial issue

iSCM – Objectives (2)

In case of biologics flexibility and resilience gain higher importance and traceability has to be further developed towards full transparency



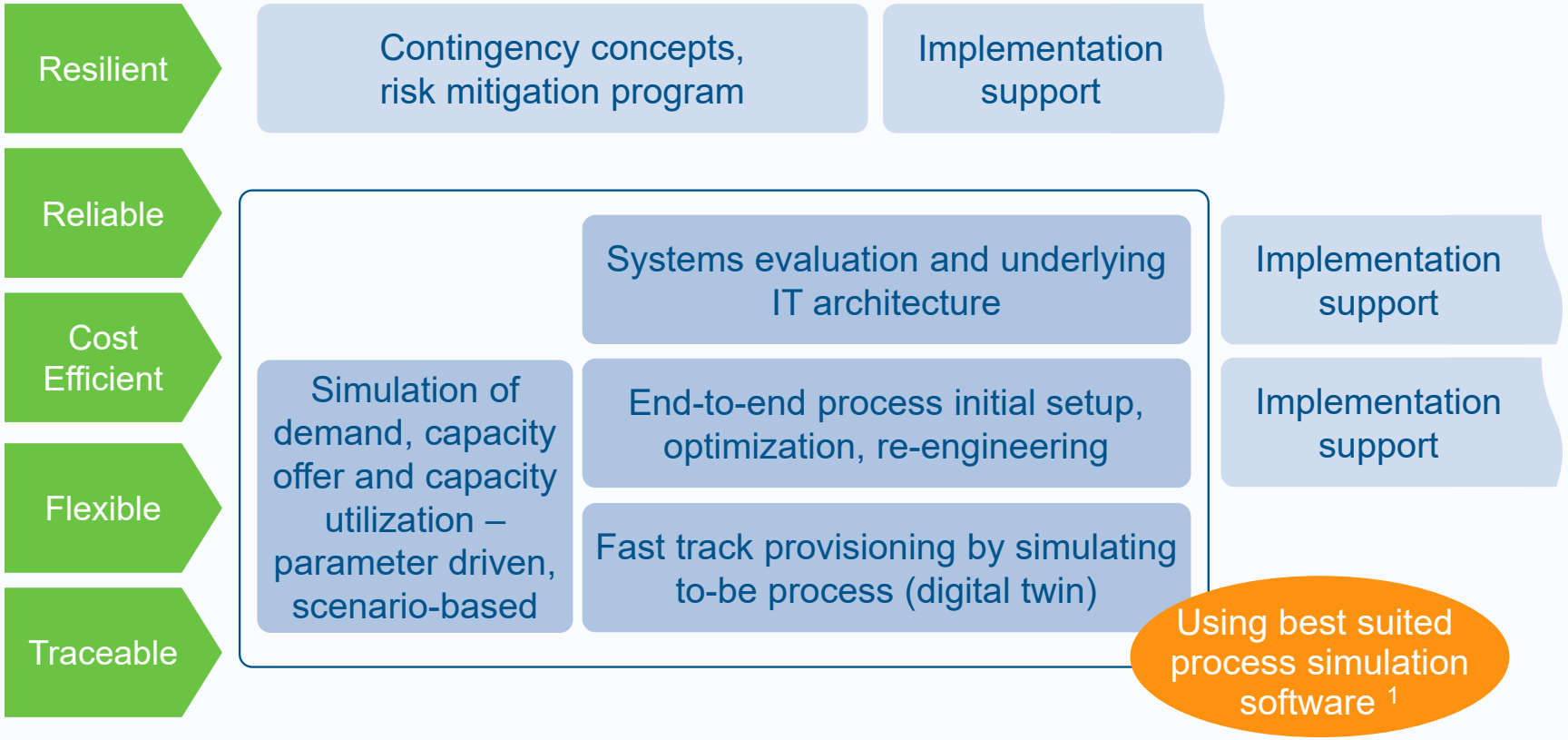
iSCM – Challenges

Amount and dimension of challenges make life not easy

- Global trends force the setup of several supply chains – in the worst case one fully-fledged chain for each relevant target market – typical product properties of biologics reinforce this necessity
- A real end-to-end process between initial collection of raw material and final administration of the product with a large number of handoff points and partners involved has to be designed, managed, and strictly monitored
- At the beginning of implementing the supply chain most of hand-off points are organized manually leading to high risk of failure and safety issues – the following scaling up is very often underestimated
- Biologics have some demanding characteristics: very sensitive products or product components, with cooling requirements (ultra low temperature), need for seamless traceability, complex and therefore error-prone sub-processes in the supply chain itself
- High uncertainties in the demand require a scenario-based, fully integrated and – if possible – real-time demand and capacity planning process
- IT has high value contribution potential and ranges from complete automation of processes, use of track & trace systems with data loggers and alarm points, through provisioning an integrated data platform, to AI-based advanced data analytic software

iSCM – Services of JSC

JSC brings idea to productive life by fast modelling and simulating the "system and its dynamics"



Digital Twin – is a digital representation of a physical object, process or entire system, (1) e.g. Process Simulator, iGrafx, InoSim

iSCM – Project Example (1)

The “optimization of a given supply chain” requires approx. 4 months

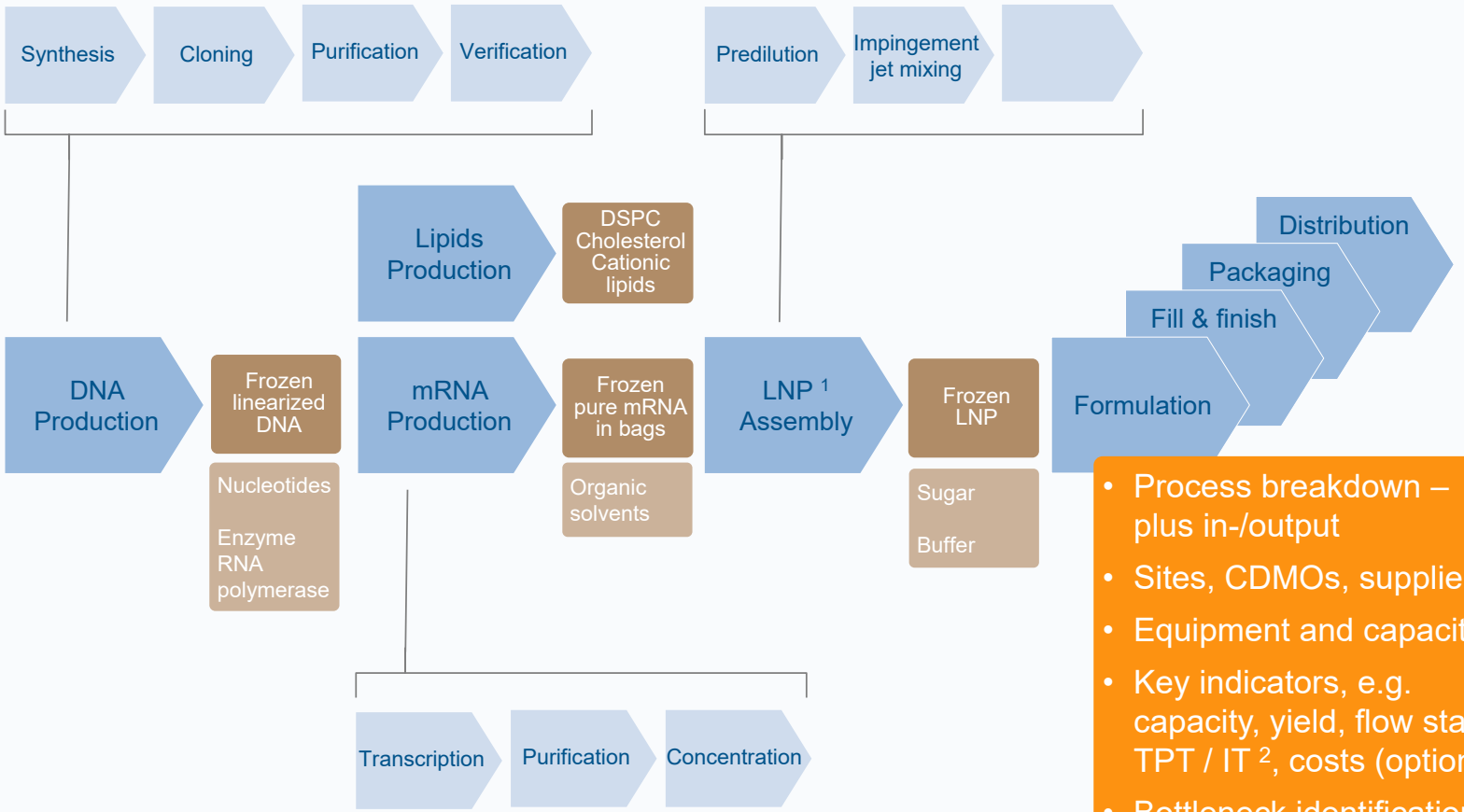
1 month	1 months	2 months
Phase 1 Product characteristics and status of the current supply chain Requirements on the future supply chain Data acquisition and initial model setup	**Phase 2** Specify target parameters and values ... and understand their dependencies Consider industry [1] benchmarks Map parameters in the model	**Phase 3** Start the simulation process … taking into account different SC scenarios and different fulfillment of target parameters Assess scenarios and recommend "the best"
Project kick-off 2 content workshops	3 content workshops	4 content workshops 1 hand-over meeting Presentation to SteerCo

Effort driver
technologies
products / SKUs
process steps
sites & partners
markets …

(1) Companies in Biotech, Pharma, Process Industry and Industries with batch size one

iSCM – Project Example (2)

The supply chain (simplified) in case of mRNA based vaccines

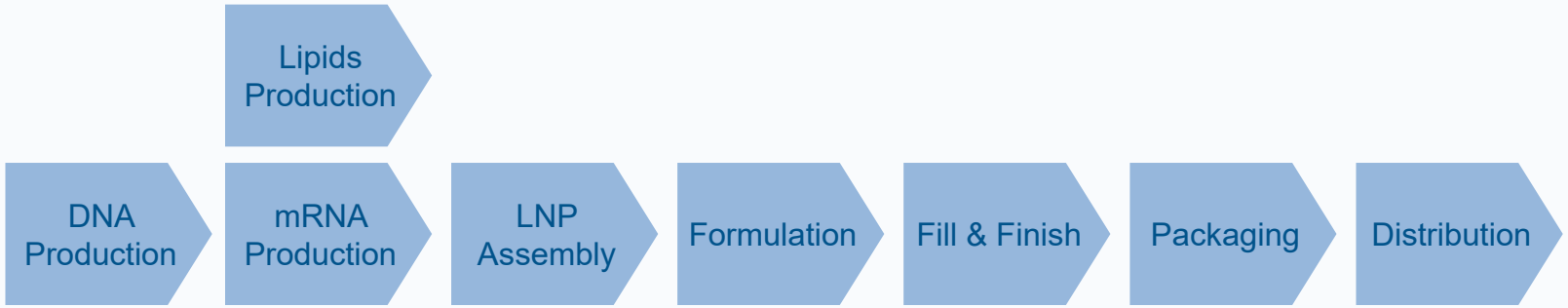


- Process breakdown – plus in-/output
- Sites, CDMOs, suppliers
- Equipment and capacity
- Key indicators, e.g. capacity, yield, flow stability, TPT / IT [2], costs (optional)
- Bottleneck identification

(1) LNP – lipid nanoparticle, (2) TPT / IT: Throughput Time / Idle Time

iSCM – Project Example (3)

Focus of optimization can be different depending on identified paint points



- Avoidance of out-of-stock situation by managing bottlenecks adequately
- Better capacity and demand balancing considering volatile demand scenarios
- Reduced overall throughput time
- Identification of process productivity options
- Conversion cost reduction per jab
- Tougher mastery of the partner structure

Contact

Please feel free to contact our experts in Technical Operations

Dr. Ulrich Tulowitzki
Management Consultant
BA TO

utu@jsc.de
+49 (0) 179 400 10 47

Norbert Skubch
Director BA TO
and Chairman of the
JSC Supervisory Board

nsk@jsc.de
+49 (0) 172 407 57 02

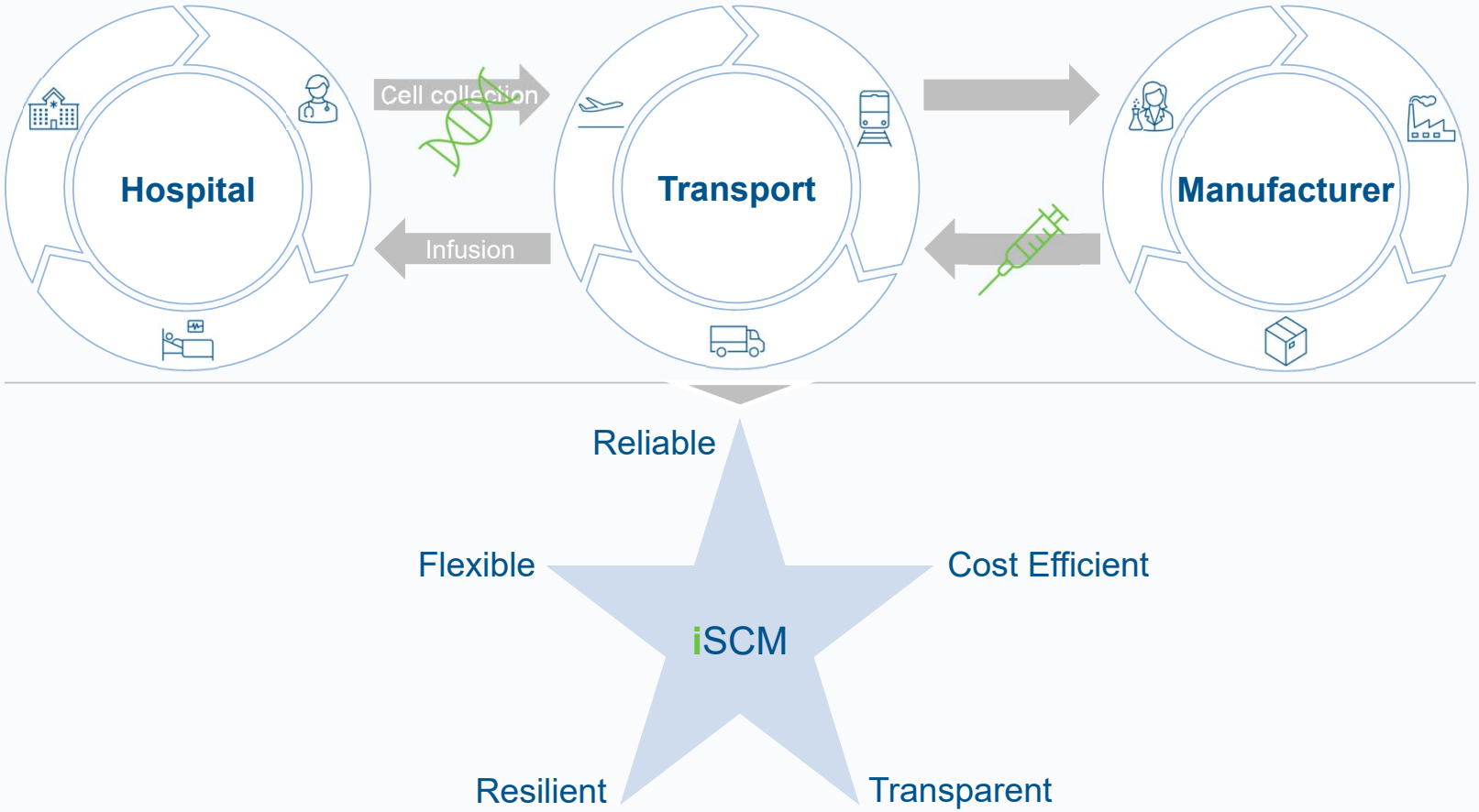
Elmar Schipp
Director BA TO
and Head of BA TO

els@jsc.de
+49 (0) 174 320 65 70

BACKUP

Supply Chain for CGT – End-to-End Process

The end-to-end supply chain of cell and gene therapies (CGT) has to be managed along well defined quantitative KPIs per objective



JSC Management- und Technologieberatung AG
Im Pfarracker 24
65346 Eltville am Rhein
Germany

Phone + 49 (0) 6123 / 701 - 0
Fax + 49 (0) 6123 / 701 - 170
E-Mail info@jsc.de