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U.S.-GERMAN STANDARDS PANEL 2016

INNOVATION IN THE MEDICAL DEVICE SECTOR

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INNOVATION IN THE MEDICAL DEVICE SECTOR

For presentations, please refer to:
www.din.de/go/us-german-standards-panel

PROGRAM

APRIL 11th

RESTAURANT
Darlington House
1610 20th St NW
Washington, DC

6 WELCOME DINNER

Guest speaker:

8 ***Dr. Thomas Zielke,*** *Representative of German Industry and Trade (RGIT) in Washington D.C.*

APRIL 12th

VENUE
FHI 360 Conference Center
Academy Hall
1825 Connecticut Avenue NW
Washington, D. C.

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11 WELCOME ADDRESS

Rüdiger Marquardt, *Member of the Executive Board, DIN*

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Fairmont Hotel
2401 M St NW, Washington,
DC 20037

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APRIL 13th

Gaithersburg,
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WELCOME DINNER

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• Joe Bhatia

• Susanne Gellert, Heike Moser

• Dezso Csipo, Greg Orloff

• Susumu Nozawa, Elisabeth George, Jessica Roop, Carol Herman, Sibylle Gabler, Joe Bhatia, Rüdiger Marquardt, Dr. Thomas Zielke

• Carol Herman, Katharine Morgan

• Pamela Gwynn, Prof. Dr. Jörg-Uwe Meyer

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APRIL 11th

• Gordon Gillerman, Katharine Morgan, Joe Bhatia

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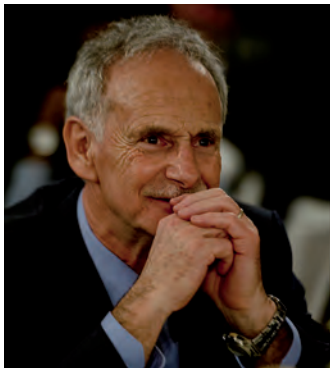

• Hermann Riesenberger

• Dr. Ulrike Bohnsack

• Oliver Deiters

• Jospeh Tretler, Ryan Crane

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• Anton Keller, Heike Moser

• Rüdiger Marquardt, Dr. Thomas Zielke, Joe Bhatia

• Dr. Ulrich Romer

• Dr. Cord Schlötelburg

OPENING REMARKS

Dr. Thomas Zielke
President
Representative of German Industry and Trade

→ The Representative of the Federation of German Industries and the German Chamber Organization are fully focused on manufacturing. And that's why we appreciate all efforts maximizing the compatibility of standards and regulations in order to let the transatlantic markets run as smoothly as possible – for the benefit of producers, consumers, share-holders and workers at the same time.

The compatibility of internet based solutions, and a framework for data flows and data protection requires innovative regulatory and standardization solutions. Meaning the more advanced the devices will be: The regulators as well as the standard setting institutions have to be as much forward thinking as the engineers are. Not just follow. Since US and European – and of course German – manufacturers particularly are on a level playing field, we can influence the world standards and shape the regulatory environment, a unique opportunity we should take.

Framework and conditions are excellent
German Industry in the US is ready to contribute to progress on both sides of the Atlantic. Because basically the general conditions in the US are sound and promising for foreign investors. Growth rates still fluctuate, but the economy has added more and more jobs. According to our German American Business Survey 2016 presented in New York in December 2015:

- 97% of German companies in the US expect revenue growth!
- 75% plan to expand their workforce!
- In 2015 the United States have become # 1 export destination for Germany for the first time since 1961.
- German Investment in the US climbs to 224 Billion Dollars.
- 640,000 Jobs are provided by German companies in the US, a new record.
- U.S. exports to Germany rose by 4.2%

Trade Agreements are a chance to talk standards
You know of course that the 12 countries that have signed the Transpacific Partnership last month in New Zealand have agreed on a bunch of new trade rules that will tackle among others trade barriers, customs duties, IPR rules, Geographic indicators, labor rules and many more. Not so much regulatory cooperation or standard setting, procedures or mutual recognition.

This means on the Atlantic site we still remain in the lead; even if the TPP agreement hopefully will be adopted sooner or later but likely earlier than a TTIP that is not even completely negotiated.

With regard to standards we firmly believe as such from the viewpoint of the German Industry Federations that it would be essential to agree as far as possible to a few fundamental cornerstones. Such as

- Setting up a harmonized transatlantic legal framework.
- Observing WTO criteria for removing non-tariff barriers to trade: These criteria are based on the national delegation principle and recognize ISO and IEC as the only international standards organizations. ISO and IEC Standards should be adopted at the national level.
- Taking the demands of industrial sectors into account: Both European and US standards setters must refer to the relevant ISO or IEC Standards.
- However it would be falling short by calling just for "mutual recognition" of standards. Because we would have certainly concerns about agreeing on a rule that basically could hurt the achievements of the most successful example for peacefully harmonized economies.

By the way we also believe the single market benefits the 3.000 American companies that are present in Germany alone. Not to speak about the rest of Europe. Even for smaller US companies the advantage is clear: market access in France means market access to Germany, Holland, Belgium, Poland etc.

Medical Device Industry

I am glad you chose the medical device sector for the upcoming conference. First: Because it's a good example for many problems in the transatlantic trade environment, that – if they would have been solved – could foster a whole new spirit of entrepreneurship and innovation by eliminating the obstacles alone.

Second, because our two countries or regions including the EU count for far more than 50% of the relevant world-market, with 38% for the USA alone and 15% for Germany according to German Governmental and industry related statistics. And third: Contrary to some assumptions it is indeed an SME driven sector, in which 80% of all companies have less than 50 employees.

Safety and quality are the hallmarks of the products in the medical device industry. Still, there are different technical requirements for products and their production on both sides of the Atlantic. They guarantee a comparable level of product safety and quality to consumer and environmental protection requirements. Still though, the testing, inspection and certification procedures may differ dramatically. This results in complex, costly and partially redundant processes that impede access to the U.S. market for German and European companies. It furthermore increases the cost of production, R&D and raises prices for consumers. The same applies to US products and access to the European market.

We have examples, given to us from companies, where for instance a single company of smaller size just has to pay almost a million Dollars each year for double certification procedures.

TTIP now offers the chance to the mutual recognition of approval procedures in this sector, so that they contribute to the creation of a comparable, high level of protection and compatibility. Better cooperation between regulators and standard setting agencies would help to bring medical products to the markets faster and for the benefit of the patients: granting them fast access to innovative and safe technologies. This is a true case of where enhanced and standardized approval procedures and product standards are a real driver for innovation.

Health care suppliers told us with regard to TTIP that all kinds of agreement that allow them to launch their products with the highest safety and quality standards with less cost or bureaucratic hurdles into the market, will increase their competitiveness. Since they increasingly are active on both sides of the Atlantic anyway, this would increase competitiveness as such, and at the same time could shape world standards because of the sheer size of the market.

Recently my organization has provided a formal statement to TTIP stake holder events: Among these measures are:

- Avoiding divergent standards or convergence of technical standards
- Avoiding double certification
- Core regulatory cooperation, including corresponding impact assessment and early warning mechanisms

The potential is tremendous: In Germany alone one out of five jobs depend on the healthcare-sector, the growth rate and the share from GDP are over-proportional compared to the general GDP ratio. The numbers in the US are very similar. The medical device sector fosters innovation by spending 9% of its turnover back into R&D. Chemical-industry for instance still highly innovative invests just 5% back into R&D. Hundreds of thousands if not millions good paid jobs offer a bright future for skilled workers.

So let's save this asset for our economies and let's strengthen it, by finding those solutions that help us to grow. I appreciate that your organizations have chosen to show leadership in this respect, and I wish you every success for tomorrow's conference.

WELCOME ADDRESS

APRIL 12th

Joe Bhatia
President and CEO, American National Standards Institute (ANSI)

→ Standards and conformance play a critical role in the economy, impacting more than 80% of global commodity trade. In 2015, that 80% impact came to more than 14 trillion dollars for the U.S. economy.

It is clear that effective utilization of globally relevant standards and conformance promotes technological interoperability and the competitiveness of all businesses. And greater cooperation and information-sharing will improve the bottom line – clearly a top priority in today's economic landscape.

So what do I mean when I say "globally relevant standards?"

The U.S. endorses the globally accepted standardization principles of the World Trade Organization's Technical Barriers to Trade Agreement, which include openness, balance, consensus, and transparency, among many others. We believe that – as long as these principles are followed – a high-quality, globally relevant standard will emerge, regardless of which standards developing organization – or which nation – produced it.

ISO and IEC are some of the most recognized names in standards development, but it is important to note that other SDOs are also developing high-quality, globally relevant standards, and in some cases, have been doing so for well over 100 years.

Especially in the medical device field – which is the focus of our discussion today – you have companies that develop, manufacture, and distribute their products and services all over the world. This means that reliance on globally relevant standards and conformance programs is imperative. Otherwise, you have products, personnel, systems, and services that cannot cross borders.

That is why standards and conformance are so important to the continued health of the excellent trade relationship between the U.S. and Germany. In 2015 alone, the U.S. exported nearly 50 billion dollars in goods to Germany, and in turn, imported over 124 billion dollars in goods from them.

Compare these to figures from ten years ago, when exports to Germany totaled 31 billion dollars, and imports from Germany were valued at about 77 billion dollars. These figures demonstrate that our German friends started with an advantage and have been able to maintain that edge. Still, I believe we have come a long way in this key trade relationship. And as the components of Transatlantic Trade and Investment Partnership (TTIP) continue to be negotiated – and when they are implemented – the importance of our relationship is only going to continue to grow.

The U.S. standardization community is truly committed to fostering the global partnerships that lead to the greatest advancements for all stakeholders across borders and industry sectors. If there is one key element that is critical to developing the strongest solutions, it is broad participation. When all perspectives are present at the table, the most robust and effective standards and conformance solutions emerge.

Harmonized standardization between the U.S., the EU, and Germany will benefit the transatlantic market as well as global trade. Our international collaboration can foster comprehensive solutions to address some of the technological, economic, and societal challenges that we all face.

We are so pleased to have a terrific turn out for today's roundtable discussion. I look forward to hearing from all of you, and to continuing to work together in the future. Thank you for your attention.

WELCOME ADDRESS

Rüdiger Marquardt
Member of the Executive Board, DIN

→ The importance of transatlantic trade in medical technology between the U.S. and Germany continues to rise. For many years now, the USA has been the most important market for the German medical device industry. In 2014 Germany exported medical devices in the amount of 4.6 billion U.S. dollars to the USA. Medical technology from overseas is in high demand in the USA: In 2014 imports rose by 5.4% to total 45.3 billion US$. The total market volume in 2014 is estimated at 121.6 billion US$. Conversely, in the year before that, medical devices valued at 3.2 billion euros were imported from the U.S. into Germany.
In short, the U.S. are our most important trade partner for medical devices.

As the baby boomer generation ages and the medical technology industry continues to bring forward new innovations, so the market is expected to grow on both sides of the Atlantic.
It is no wonder, then, that the medical technology sector is following the negotiations on the transatlantic free trade agreement with great interest. TTIP can mean additional growth potential for medical devices, a sector that relies heavily on exports. TTIP is an opportunity for the USA and Europe to further enhance the mutual recognition of certification and market access procedures for medical devices. We are eager to hear today what the negotiators from the European Commission and USTR have to report about the progress of the negotiations. We are also eager to listen to what companies and certifiers will say to us about using standards to meet regulatory requirements.

The environment in which innovative medical devices come about is far more complex than in many other sectors. This applies not only at the level of research and technology but also to clinical testing, certification for market access and market penetration. Standards can help reduce this complexity. They can help ensure that innovative medical devices with corresponding benefits to patients gain faster access to a regulated market. Together with scientific researchers and representatives from industry, the German Federal Government has developed a national strategy on "Innovations in medical technology". The resulting White Paper underlines the importance of standards when creating interfaces in networked systems.

Another important aspect that deserves mentioning here is the fact that standardization is a tool that allows small and medium-sized enterprises to play a strong and important role.
In Germany some 1200 small and medium-sized companies form the innovative backbone of the medical technology industry alongside some big players.

I have focused on two convictions that are the basis of the U.S.-German Standards Panels and our ongoing transatlantic discussion:

- Standards support market access for innovations,
- and harmonized international standards support international trade.

During the Standards Panel in 2013 we came to an interesting conclusion which combines the two convictions:
Bilateral transatlantic standards in highly innovative areas could be a new way forward in supporting our innovative industries and their transatlantic trade prospects. At the same time they would prepare the ground for disseminating knowledge via international standards of ISO and IEC. Maybe today's Standards Panel will give us input for possible transatlantic standards in highly innovative areas.

KEYNOTE SPEECH

Electronic Health/Medical Records: Recent Developments and Implications for Standardization and Public Policy

Tim Büthe
Associate Professor of Political Science and Public Policy, Duke University

→ The development of electronic health records (EHRs) holds tremendous promise, including improvements in the quality of care through better decision support and reduced risks of medical errors, costs savings due to the elimination of duplicate testing, and vast new opportunities for medical research that may lead to new and better treatments. In the United States, great progress has been made in the development and adoption of EHR systems in the twelve years since the push for electronic medical records was launched as a genuinely bipartisan effort in 2004. Yet, the lack of standardization of important aspects of EHR systems has severely restricted the gains from the move to EHRs, which are often incompatible not just across countries but even within countries, from large ones such as the United States to some small countries such as Israel (which has 27 different EHR systems). At the same time, the fully interoperable EHR systems of Denmark, Norway and Sweden show that even international EHR systems integration is in principle possible.

Achieving the full benefit of EHRs requires further efforts in the realm of standardization – in close and conscious coordination with supportive public policies. Thanks to tremendous efforts at standardization, a number of technical feasibility challenges, for instance, in the communication between differently structured EHR databases, have already been addressed. Some work remains to be done on the purely technical IT side, but more – and more challenging – work remains to be done in the realm of biomedical terminology standards, which constitute the conceptual backbone of any EHR but still differ across a number of the EHR systems, in some cases reflecting different concepts of health, so that different biomedical terminologies may lead to rather different, incompatible EHRs. Past experience suggests that the market process alone is unlikely to resolve such incompatibilities between different standards, particularly given strong commercial stakes in maintaining multiple incompatible systems. At the same time, when governments decide that it is necessary to intervene in markets, they should do so more consciously and openly than occurred, for instance, when the U.S. government co-founded the International Health Terminology Standards Development Organization (IHTSDO) to take public, international ownership of one of the key biomedical terminology standards, SNOWMED-CT. Technical experts also will need to work closely with policymakers to recognize and address concerns about human error and privacy, as well as important challenges at the intersection of law and public policy. One key impediment to U.S. physicians' willingness to create comprehensive and accurate health records – concerns about the patients' ability to obtain/maintain health insurance if his/her health record were to disclose possible "pre-existing conditions," was resolved by the prohibition of denying coverage for such conditions. Should new political majorities in Washington after the 2016 election repeal or replace "Obamacare," policymakers better ensure that this element of the healthcare reforms is retained, lest they do irreparable harm to the U.S. EHRs. The other key impediment, which is also an issue in some other countries, such as Germany, is medical liability: If EHRs can readily be used to bring malpractice suites against physicians, it creates incentives against recording complete information about treatments, risks, and errors in the patient's EHR, greatly diminishing the benefits of EHRs. Policymakers need to recognize and address this connection.

MODERATORS

• **Sibylle Gabler**

• **Gordon Gillerman**

• **Hermann Behrens**

• **Carol Hermann**

SESSIONS

1.
THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP)

2.
STANDARDS IN THE EU AND US – A TOOL FOR MEETING GLOBAL REQUIREMENTS

3.
INTEROPERABILITY IN THE MEDICAL DEVICE SECTOR

4.
INNOVATIVE FUTURE TOPICS

1. THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP)

MODERATOR: **Sibylle Gabler** · Senior Manager Government Relations, DIN

TBT Chapter and Annex on Medical devices

Isabel Pastor Arenillas
Trade Counselor, EU Delegation to the USA

U.S. perspective

Ashley Miller
Director, Industrial Goods Market Access (TTIP sectors), USTR

2. STANDARDS IN THE EU AND US – A TOOL FOR MEETING GLOBAL REQUIREMENTS

MODERATOR: **Gordon Gillerman** · Director, Standards Coordination Office, NIST, US DoC

Harmonized Standards (EU)

Matthias Marzinko
Director International Standards Management, Drägerwerk AG & Co. KGaA

Main differences between Harmonised and Recognized Standards

EU HARMONIZED STANDARDS	U.S. RECOGNIZED STANDARDS
One list of standards, manufacturer has to choose the applicable standards to fulfil essential requirements. EN Annex ZZ as reference	Recognized consensus standards sorted according speciality and product code. Extend of recognition is listed per standard
Valid for new registrations, changes and legacy devices	Valid for new registrations (incl. subst. equivalence 510(k) and changes
No direct involvement in standardization process by EU commission. Stipulation of standardization work via CEN CENELEC to the European National Committees	FDA with direct participation in standards on national and international level. Involved in the standard creation process.

Recognized Standards (US)

Scott Colburn
Director, Standards,
US FDA

→ Scott Colburn provided a brief over view of the CDRH Standards Program which was established as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. The program contributes to the Center's mission of protecting and promoting public health through the development and recognition of voluntary consensus standards that serve to establish safe and effective medical devices, radiation-emitting products and emerging technologies.

Conformity Assessment – Keys to Multiple Market Access

Royth von Hahn
Global Director Functional Safety and Software, Medical and Health Services,
TUV SUD Product Service Division

→ Looking for universal market access, harmonization of product requirements is the key. For the highly regulated medical device market it is necessary to understand how standards interact with the regulatory frameworks and how these frameworks can be aligned to simplify multiple market access or at least reduce the regulatory burden on manufacturers.

The regulatory scheme defines the regulatory process (what needs to be done and who is doing it) and the regulatory (technical) requirements for manufacturer processes and products. There are three general options for harmonizing regulatory frameworks: system harmonization, mutual recognition and convergence of schemes.

In the field of technical product requirements the international standardization organizations facilitate the technical standardization and with increased participation of regulatory agencies and authorities, good progress is achieved in this field. It is more difficult to align the understanding of the "state of the art" or the "reasonable" achievable risk reduction.

Process-wise, there is already a widely accepted basis for quality management in medical device industry which is ISO 13485. Thanks to the IMDRF (former GHTF) there is a recently introduced single audit program (MDSAP) covering 5 markets (USA, Canada, Brazil, Australia, Japan) with the EU as observer. From TUV SUD own experience with MDSAP this can be combined with the QM assessments for other ISO 13485-based schemes like the MDD.

So there are successful harmonization efforts for product requirements and quality management. For the overall alignment of schemes there is a fundamental difference: having an authority deciding on each and every device by registration/notification/approval in the USA compared to the manufacturer self-declaration approach (with involvement of 3rd parties) in Europe.

Due to the legal inconsistency between these two regulatory approaches, it is unlikely that a complete legal harmonization of systems can be achieved. Mutual recognition seems easier but is actually similar difficult to be implemented because even with comparable product safety, there are open questions of responsibility and liability.

Therefore the convergence of schemes is the way forward with those promising initiatives like UDI, MDSAP and consensus standards. Innovations need additional attention since they are usually not covered by established standards or specific requirements and need ad-hoc assessments and decisions. A further challenge is digitalization and interconnection since aspects of IT security are introduced that are not completely covered in the medical device related regulations and standards. Instead they are covered in other directives/regulations. Not only that those might not be aligned internationally (like IT security or privacy), they may also contradict with specific medical regulation within the respective region.

What Global Companies are Doing

Elisabeth George
Vice President of Global Government Affairs, Standards & Regulations, Philips Healthcare, USA

→ Philips is a global company that designs, manufactures and distributes consumer and medical products and solutions. Philips is involved in standards development and utilization and values having partnerships. All stakeholders want safe and effective solutions in a timely manner. With every country having differing processes, requirements for deliverables (particularly test data) the result is unpredictable time to market.

Convergence through standards will support predictability in outcomes, performance and time to market. Use of standards allows for common language. Use of standards should be the basis for trade alignment and ultimately supports cost savings, which will help improve patient access to healthcare technology. The same challenges are being faced by all stakeholders – whether they be participation challenges, length of time-to-availability or adoption. Due to these challenges it is important to find new and progressive ways to develop standards to support the needs. It's important to be ahead of the technology and not slow progress and innovation down. It's important to consider conformity assessment when developing a standard. Most importantly, all stakeholders must be engaged to ensure the optimal outcome.

STANDARDS IN REGULATION – USE CASES

Current issues – disposable medical products

Herrmann Riesenberger
Head of Working Group Standardization, BVMed,
The German Medical Technology Association

→ Standards are technical specifications defining requirements for products, production processes, services and test methods. These specifications are voluntary, developed by industry and market actors following some basic principles such as consensus, openness, transparency and non-discrimination.

International standards bring technological, economic and societal benefits. They help to harmonize technical specifications of products and services making industry more efficient and breaking down barriers to international trade. Conformity to international standards helps reassure users that products are safe. All this can be achieved only if all parties involved follow consensus and rules.

In the presentation – three typical use cases are highlighted were manufacturers seek improvement and solution:

Case 1 highlights different requirements for Biocompatibility Test between ISO 10993 series and FDA required test at recent 510k application which leads to delay in product launch and additional cost.

Case 2 highlights new FDA requirements "Critical to Quality Indicators" applied in an audit for Intravascular Catheter recently. These are additional requirements compared to respective ISO 10555-1 and ISO 10555-5 reworked and issued 2013-06 and confirmed as FDA recognized consensus standard. The relevant standards are developed in ISO TC 84 / WG9 under participation of FDA delegates. It is this WG where such additional requirements should have been addressed, respectively to be addressed for update in the future.

Case 3 highlights an added dose accuracy testing in ISO 11608-2 version 2012-02 for pen needles which discriminates some needle manufacturer. As pharmaceutical cartridge supplier only open for single cooperation with NIS and needle supplier to provide test material and open for change control agreements, other manufacturers will have limited access to market. Pen needles do not have impact to dose accuracy. The influence of flow rate can be tested and provided.

ISO standard should not allow requirements which are not open, not transparent and not non-discriminating.

UL: Solutions for Medical Device Companies

Pamela Gwynn
Principal Engineer for Medical and Home Healthcare Equipment,
Underwriters Laboratories (UL)

→ Electrical Medical Equipment manufacturers' face many challenges to get their products into the global marketplace. These challenges include both understanding the regulatory landscape in the global marketplace and compliance with the medical electrical standards. Each of these challenges present opportunities for Underwriters Laboratories (UL) to partner with the manufacturer to assist in getting products to market.

Global Regulatory Landscape
Producing a product for worldwide distribution can be challenging as it relates to understanding all the Regulatory requirements across the globe. UL partners with the customer to understand their target markets and leverages our experts in the various countries to assist the customer in understanding the regulatory requirements. In emerging markets UL will research regulatory requirements and provide up-to-date information.

Compliance with Medical Electrical Standards
Most electrical medical equipment and electrical medical systems utilize the 60601 series of standards. However, there are times when a product has features that are not addressed by the standard. Manufacturers are concerned that they will not be able to place products onto the market due to this issue. UL can and does certify products with features not currently addressed by the standard. First, UL will partner with the electrical medical device manufacturer to understand the unique issue of the device. Once this understanding is reached, UL will work to address the hazard by again leveraging the expertise of our global staff to determine if published requirements exist in other standards, such as AAMI, IEC, ISO etc. When requirements exist in other standards, UL will look to use them. When requirements do not exist, UL will work to establish requirements, both construction and performance. These requirements are presented to the manufacturer for discussion. Once the additional requirements are finalized, the medical electrical equipment is evaluated to the 60601 series of standards and the additional requirements. After compliance with all applicable requirements is met, the product is certified to bear the UL mark. If new requirements are developed, UL will begin the process to have these requirements included in the suitable standards.

Standards and Medical Imaging

Diane Wurzburger
Executive, Regulatory Affairs, GE Healthcare/MITA

→ Standards are important to the medical imaging industry in a variety of ways. MITA standards are for use by industry, regulators, and conformity assessment bodies in measuring performance, assessing quality, and guaranteeing safety of medical imaging equipment. MITA plays a lead role in key national and international standards used by the medical imaging industry to enable interoperability of devices in the imaging suite (DICOM), set safety and effectiveness standards (IEC 60601 suite), and assess cybersecurity of a system or device (HIMSS-NEMA HN 1). Standards can be used in tandem with regulations and legislation to fill urgent needs; for example, MITA Dose Check (XR 29) which improves worker and patient safety around ionized radiation emitted by CT scanners.

3. INTEROPERABILITY IN THE MEDICAL DEVICE SECTOR

MODERATOR: **Hermann Behrens** · Head of department Innovation, DIN

Internet of Medical Systems and IT Services

Prof. Dr. J.-Uwe Meyer
CEO, CTO, MT2IT GmbH & Co. KG

→ In an era of "Internet of Things" (IoT), "Cyber-Physical Systems" (CPS) and "Digital Health", interoperability between connected medical devices, medical IT systems and health applications turns out to be a prominent part in national roadmaps addressing modern health and care delivery. User-friendly front-ends for interacting online with the "system of systems" are becoming increasingly important for achieving better medical outcomes and safe and secure health delivery.

There have been recent national and international efforts regarding the development of standards and profiles for medical device networks connected to electronic health records (EHR) and for advanced real-time, multi-user, multi-device cyber-physical medical systems (CPMS). "De facto" web communication standards and web application programming interfaces (Web-APIs) are affecting the conventional medical device standardization process. A service-oriented hybrid-cloud concept and Web platform will is an innovative approach for cyber-physical medical software assisting surgical workflows and mobile delivery of health and care.

Implementing Information Exchange Standards in Healthcare Facilities

Dezso Csipo
President, Object Forge, Inc.

"In the medical industry we still think in silos. We do not yet think in system."

"Patients get double CT's or X-rays between different departments because these are not interconnected. An integrated system needs to take care of all verticals. The information is available to the practitioner within the facility. Once you move out of the facility everything becomes murky."

Interchange formats of medical documents – IT-specifications

Dr. Georg Heidenreich
Manager Healthcare IT Standards, Siemens Healthcare GmbH

→ Medical jargon and medical "documents" can be traced back until ancient times. But only with the use of structured, electronic formats, medical information can be kept over time and transferred between different care providers. The presentation on medical document formats introduces the various situations in patient care, where medical information is represented by electronic means.

There is a strong relationship between quality requirements and the document lifespan resulting from the respective underlying use-case:

1. A specific patient care situation is the context for a short clinical note or order or patient device reading, which has a lifespan of not more than one day and a reach of a single department.
2. A clinical report or finding is a document related to a clinical workflow step and normally does not exist longer than one week.
3. A medical summary is related to an episode of care (a clinical encounter) and may be used for some months and in a limited area outside of the hospital or GP office where it was created.
4. A patient record is a document for long-term use and a wider geographic scope – maybe even international.
5. A citizen's health record is a document for life-long use and global reach.

Along with this scope, (as less and less context exists) the quality requirements become stricter and stricter.

From the respective standards-developing organization for these different types of documents we derive related requirements for the underlying standards development process itself: The "larger" the document scope, the "higher" the quality, the stronger the needs for consensus and stability of the SDO. We conclude that for high-quality documents, only the ISO/NMB-system can guarantee to deliver appropriate standards. In many cases, authority-driven standards lack consensus of market players – which later turns out to be an obstacle towards implementing and investing. As there are different players in medical document standardization, there need to be an optimum assignment of roles and duties.

Safety and Security Standards for Medical Application Platforms

John Hatcliff
University Distinguished Professor, Department of Computing and Information Science, Kansas State University

→ The concept of "system of systems" architecture is increasingly prevalent in many critical domains. Such systems allow information to be pulled from a variety of sources, analyzed to discover correlations and trends, stored to enable real-time and post-hoc assessment, mined to better inform decision-making, and leveraged to automate control of system units. In contrast, medical devices have often been developed as monolithic stand-alone units. The move-

ment toward devices with connectivity is accelerating, but the vendor and regulatory communities are still searching for appropriate architecture principles that allow devices with connectivity to be flexibly composed into interoperable systems following sound engineering principles that provide appropriate levels of safety and assurance.

The emerging notion of "medical application platform" (MAP) provides solution strategies to address these challenges. A MAP is a safety- and security-critical real-time computing platform for

(a) integrating heterogeneous devices, medical IT systems, and information displays via a communication infrastructure and
(b) hosting application programs (i.e., "apps") that provide medical utility via the ability to both acquire information from and exert control over integrated devices, IT systems, and displays.

AAMI/UL 2800 aims to fill a gap in the standards space by providing safety/security requirements for interoperable medical systems. It provides guidance to the evolution of implementation standards and regulatory guidance.

There are principles necessary (but not sufficient) for supporting regulatory and third-party certification regimes that provide notions of compositionality and reuse of component assurance arguments across regulatory submissions.

Medical Robots

Mike Yramategui,
Fellow Regulatory Engineer, Intuitive Surgical, USA

→ Robotic technology is increasingly being incorporated into medical devices over a wide range of applications, and at the same time the interconnection of medical devices is becoming more prevalent. The interoperability of devices incorporating robotic technology presents potential new benefits along with potential new risks.

The "Medical Robot" terminology is not yet defined:
- IEC-ISO work on particular standards is underway
  – Surgical Robots: JWG 35
  – Rehabilitation Robots: JWG 36
- Definitions and scope are being discussed and refined
- Terminology will continue to evolve around specific applications and technology

The da Vinci Surgical System is a robotic assisted surgical device. There are potential challenges of future implementations:

Table Motion:
- Allows repositioning of the operating table with instruments installed by coordinating system motion
- Coordinated motion reduces time required to remove and reinstall instruments and facilitates:
  – Optimal position of table so that gravity exposes anatomy
  – Reach and access to anatomy, and ideal working angle
  – Precise positioning over the table's wide range of motion
  – Repositioning of the table to enhance access to patient
- Utilizes custom wired /wireless interface to "pair" table with system

Imaging:
- Enhanced imaging capabilities may allow surgeons to better identify key structures in real-time
  – Use of contrast and other markers
  – Overlay of imaging information from other equipment
- Interoperability challenges will depend on
  – What the information is used for
  – How the technology is implemented

Conclusion:
- Expanded use of web based connectivity will depend on where it adds value
  – Integration of system and hospital data for the benefit of the healthcare organization
  – Provide real-time input into surgeries remotely
  – Need to balance with cybersecurity risks
- Availability of connectivity standards will facilitate adoption for lower risk applications
- Custom implementations will most likely will be used for high risk applications

4. INNOVATIVE FUTURE TOPICS

MODERATOR: **Carol Herman** · Senior Vice President, Standards & Policy Programs, AAMI

Safe and Dynamic Networking in Operating Room and Hospital

Björn Andersen
Research Assistant, University of Lübeck Institute of Medical Informatics

→ Today's operating room (OR) contains many medical devices with highly sophisticated functionality that constantly measure and generate data. This data, however, is hardly shared with other devices or components, especially not with those from different manufacturers. To enable vendor-independent interoperability of point-of-care medical devices, open standards for a service-oriented architecture of networked medical devices are being developed.

The IEEE 11073-20702 Medical Devices Profile for Web Service provides foundational interoperability – the ability to exchange data. This data being modelled in accordance with the IEEE 11073-10207 Domain Information and Service Model facilitates structural interoperability by specifying a common syntax for device data. Providing descriptive terms from the IEEE 11073-1010X series of Nomenclature standards and modelling the devices according to IEEE 11073-103XX Device Specialisations enables machine-interpretability of the data, so-called semantic interoperability. The enveloping standard IEEE 11073-20701 defines an Architecture and Protocol Binding for building a plug-and-play network of medical device systems.

The standardisation of data exchange, structure and interpretation now allows for the interconnection of point-of-care medical devices from different manufacturers in the OR, intensive-care unit (ICU), and other clinical settings. It enables the communication of clinical IT systems and medical devices, safe remote control, sharing and reusing physiological measurements as well as technical device parameters, and aggregating them over many devices in order to create more innovative functionality. Thereby, the standardised medical device communication can improve the quality of care, simplify clinical workflows, and reduce the cost of healthcare provision.

Risk Management of 3d Printed Medical Devices

Roderick McMillan
Materials Development Manager,
DePuy Synthes

Many of Your Assumptions Have Changed

TRADITIONAL MANUFACTURING	ADDITIVE MANUFACTURING
• Well Characterized Materials With Known Properties	• "New" Materials with Limited Prior Characterization
• Anisotropic Behavior	• Isotropic Behavior
• Well developed relationships between static and dynamic properties	• New and sometimes contradictory relationships between properties
• Consistent properties across standard processes and the supply chain	• Differences between AM technologies, machine models and suppliers
• Well developed "Worst" Cases	• New Worst Cases Due to Both AM Differences and New Design Opportunities

Process Characterization is Key – Standardization is Needed.

Benefits of Standards to Risk Management

STANDARDIZATION OF:	BENEFIT
Reporting Requirements	Compare Processes for Worst Case Analysis
Material Properties	Design to AM Capabilities
Process Validation Strategies	Benchmark Machines, Materials and Processes
Purchasing Requirements	Reduction of Purchasing Risk

We Need New Standards – But We Don't Need Non-Standardization Caused by Competing Standards

- US Medical Device Community is Comfortable with ASTM Standards
  - ASTM Committee F04 on Medical and Surgical Materials and Devices
  - ASTM Committee F42 on Additive Manufacturing Technologies
  - US FDA participates in the development and has recognized many ASTM Specifications
- ISO Specifications Can Be Used in Rest of the World
- My Personal Opinion – Joint ASTM/ISO specifications are the best alternative to multiple specifications

Summary

- AM Processes Move Risk From Materials Suppliers to Device Manufactures
- AM Processes Need to be Understood to Reduce Risks in
  - Material Properties
  - Device Performance
  - Cleaning
  - Sterilization
  - Software
  - Safety
- Consensus Standards Allow for the Dissemination of New Knowledge from The Experts to the General Public – Thus Reducing Risk

Biocompatibility and evolution of risk management in safety evaluation of medical devices

Dr. Jon Cammack
Global Vice President of R&D/Clinical Quality, AstraZeneca

→ ISO TC 194, the Technical Committee responsible for the ISO 10993 (biological evaluation) and 14155 (clinical evaluation) standards, contributes to public health and well-being by developing standards for medical devices and combination products, conformity with which manufacturers ensure their products do not compromise the safety of patients.

This is achieved primarily through a risk management approach by which a manufacturer can identify biological hazards associated with medical devices, estimate and evaluate the risks, control these risks, and monitor the effectiveness of the control. An essential element in adequately protecting patients also includes risk-benefit analysis.

Conclusions:

- Device biocompatibility – unique challenges
- ISO 10993 Standards promote uniformity, consistency, and patient safety
- New tools – new opportunities
- Device development experts as risk managers – can aid in reducing Serious Adverse Events

Innovation and Adaptation in the Development of Standards for Absorbable Implants

Byron Hayes
Biomaterials Research and Development,
W.L. Gore & Associates, Inc.

Synopsis

Well established markets are typically served by multiple companies, all of whom, as part of their success, have developed the needed technologies as well as a broad support system of various suppliers and subcontractors. Part of that critical support system includes universities with curriculum that supplies skilled new graduates who possess the appropriate insights and expertise to sustain the industry. In contrast, newly emerging markets and/or quickly developing technologies sometimes encounter significant shortages of both the expertise and support systems needed to move product development forward. Such shortages may be isolated to the company itself or can reflect a shortcoming of the local or national job market. In some technologies, such shortages of expertise may be global in nature.

Many of the newest and most promising technologies can be considered as highly complex by today's standards, let alone when put into a historical context. Such technologies often are made possible through the integration of multiple disciplines, all of which have to be both understood and coordinated before they can result in a final finished product. To fully understand and address what may be an initially dizzying array of variables, a sufficient level of investment is needed, which ultimately will need to be offset by the monetary rewards offered by a suitably sized market for commercialized products.

It is within this future of new, complex, and potentially confusing technologies that standards development may need to take on a new and more formative role, especially within emerging technologies where demand for expertise is great, supply is limited, and many technical uncertainties may be both present and challenging to resolve. Within this context, the robust discussions and consensus building that the standards development process offers can potentially play a major role toward guiding researchers, product developers, and – if needed – regulators through the maze of potential variables toward identifying those factors that are truly important for development of a safe and functional product. However, achieving such an outcome can be challenging when the needed expertise is difficult to access or engage, a situation that can be driven by numerous practical and logistic reasons.

To sufficiently address, be timely, and remain relevant as complex technologies such as these move forward, standards development models may need to adapt to better facilitate engagement of a limited pool of difficult to access expertise. It is within this context that a somewhat different standards development model has been generated to facilitate development of an integrated and harmonized series of standards for absorbable metals – for use as medical implants that intentionally degrade in the body. This effort, which currently encompasses guidance to fundamental researchers as well as to product developers, initially evolved from a recognition that the scope of needed expertise essentially pushes on the limits of what is globally available – well beyond the current capabilities of a single technical committee or standards development organization. What began as an initiative from single ISO working group has now adapted and evolved into a cooperative ISO-ASTM effort that now seeks and actively engages relevant academic and commercial expertise from both within and outside the normal standards development processes – an approach facilitated by utilization of online discussion resources and as well as special review sessions at strategically selected meetings and conferences.

Standardization in the field of Regenerative Medicine

Prof. Dr. Michael Doser
Deputy director, Head of development in Biomedical Engineering,
Institute of Textile Technology and Process Engineering

→ Regenerative Medicine is a quite new technology. In the second half of the last century two different technologies in the medical field made huge progress: the isolation and cultivation of living cells in a laboratory and the development of synthetic implants for the replacement of injured tissues and organs like blood vessels and valves. In the 80ies more and more efforts were undertaken to combine these developments, e.g. by trying to seed cells onto the implants for a better biocompatibility (vessels) or to functionalize them (liver). These combinations were called 'Biohybrid Organs'. The next step was to combine mostly degradable carrier materials (scaffolds) with specialized cells to whole spare tissues grown in a lab. This so called 'Tissue Engineering' created a lot enthusiasm, but very soon it was realized, that the new tissue hardly integrates into the existing healthy tissue in the patient's body.

Today Regenerative Medicine comprises all new technology, trying to stimulate, guide or evoke processes of regeneration in the body. This includes the methods described before as well as the use of stem cells or of mediators, small molecules communicating with the living tissues and guiding

the regeneration in the right direction. There is interesting success in nearly all tissues and organs, creating new hope; methods to regenerate skin, cartilage and bone are widely used in clinics. These technologies may improve or even replace many of actual medical treatments within the next 30 years.

Standardization in the field of Regenerative Medicine and especially Tissue Engineering is very active mainly at ASTM: under the title 'TEMPS' (tissue engineered medical products) working groups were established in committee F04 end of the 90ies. At that time FDA had asked the scientific community for help, when they were faced by requests for approval of products, consisting of medical devices and living, genetically manipulated cells, producing pharmaceuticals. At that time there was no regulation, how to handle these combination products, more than ever any experience. Up to now about 40 standards had been developed by ASTM in this field.

Other standard organizations had more difficulties. In ISO the discussion started in TC150 (implants) but the discussion suffered in the beginning from missing knowledge in biology. Only the co-operation with TC 194 (biological evaluation of medical devices) brought some breakthroughs and resulted in a new standard ISO 13022 (Medical products containing viable human cells – Application of risk management and requirements for processing practices). The content was intensely discussed with American (FDA), European (EMA) and Japanese authorities to enable a common acceptance of this standard.

What can be achieved with standards in Regenerative Medicine?

Due to the enormous complexity of biological systems, which are not completely understood until today, it is very difficult to evaluate and approve a product or a therapeutic process for Regenerative Medicine. Cells cannot be standardized like a screw, they are individuals and heterogeneous as the humans from which they originate. But several other aspects can be standardized:

- categories of risks to be considered (e.g. infection, tumorigenic potential),
- methods for the assessment of these products (e.g. the best animal model for a certain application),
- evaluation of scaffold materials (e.g. porosity, cell distribution, degradation, hydrogel behavior, biocompatibility),
- evaluation of the functionality of mediators (e.g. growth factors).

There are many other aspects concerning the fabrication of TEMPs like the identification of the health status of the cells in process. On a European level CEN has focused some work on incubators, bioreactors and cryopreservation processes that are needed.

Thus, even if products for Regenerative Medicine are unequally treated in our continents (as biologicals, devices, combination products or pharmaceuticals) worldwide acting companies would at least expect that the same criteria are used for approval or disapproval, so that test results will be accepted by any authority. Worldwide accepted standards, like those developed by scientists can hopefully help to get this acceptance.

PANEL DISCUSSIONS

• Carol Herman

• Prof. Dr. J.-Uwe Meyer

• Matthew Hein

• Byron Hayes

• Dezso Csipo

• Dr. Jon Cammack

"Standardization organizations will have to coordinate between the different standardizers of the world. There is a place for everybody, but we have to work on the coordination."

"If industry wants we can produce specifications bilaterally. We can do this today as fast as six months."

Rüdiger Marquardt · Member of the Executive Board, DIN

CLOSING REMARKS

"In many ways we were talking on work that we can do together."

"The key message I heard: we need to speed up. We need to make sure that all the stakeholders are on board. And an important stakeholder is the user."

Joe Bhatia · President and CEO, American National Standards Institute (ANSI)

IMPRESSIONS

• Dr. Anneke Loos

• Katherine Morgan, Carol Herman, Gordon Gillerman, Joe Bhatia, Rüdiger Marquardt

• Jeff Grove

• Dorothee Berendes, Markus Brombacher

• Jesse Jur, Erik Puskar

• Isabel Pastor Arenillas, Ileana Martinez, Gordon Gillerman

• Andrew Northup

• Greg Orloff

• Jacob Schatz, Kevin Harper

• Eric Franca

• Chandresh Thakur

RECEPTION AND DINNER

ADDRESS: **Peter Rondorf** · Minister and Head of the Economic Department, German Embassy
GUEST SPEAKER: **Elisabeth George** · Vice President Global Regulations & Standards Philips,
Brian Markwalter · Sr. VP, Research & Standards, Consumer Technology Association

• **Peter Rondorf**

• Susanne Gellert, Dr. Vera Sattelmayer, Dr. Anneke Loos

• Byron Hayes, Joseph Tretler

• Dr. Ulrike Bohnsack, Prof. Dr. Michael Doser

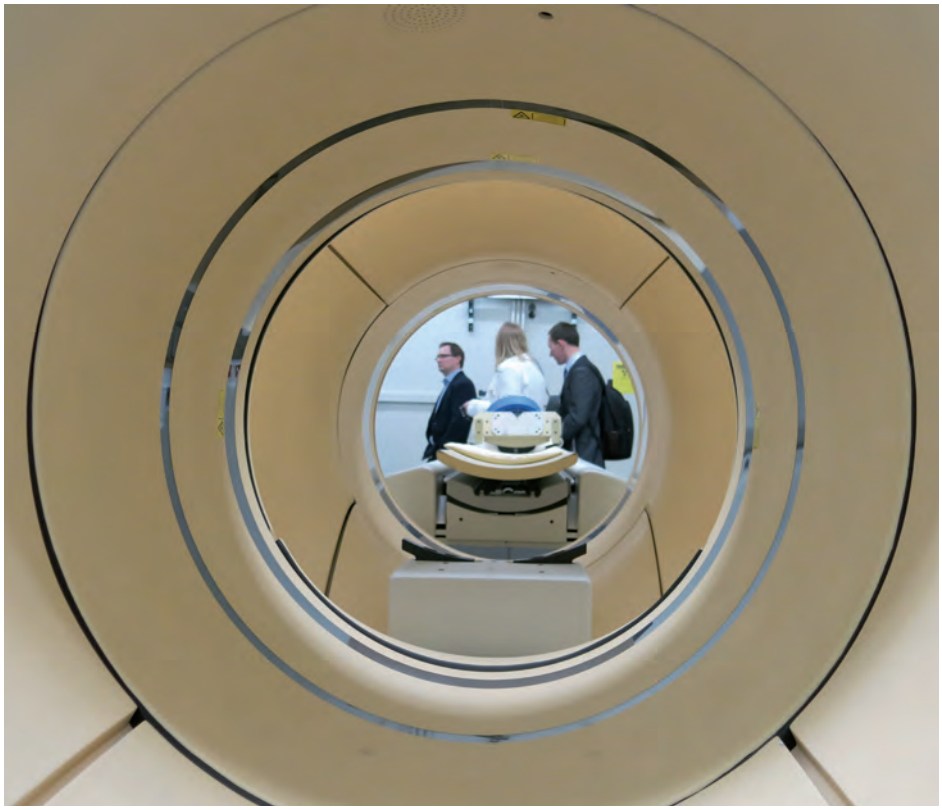
• Joe Bhatia, Brian Markwater, Sibylle Gabler

• Peter Rondorf, Rüdiger Marquardt

• Matthias Marzinko, Dr. Royth von Hahn, Prof. Dr. Michael Doser

• Kelley Cox, Stephanie Carroll

• Dr. Ulrich Romer, Hermann Behrens, Dr. Albert Hövel



TECHNICAL VISIT TO NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

Introduction to a number of NIST research activities that support innovations for medical devices · Gaithersburg, Maryland

APRIL 13th

List of participants

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Food and Drug Administration (FDA)

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