Mastrangeli et al.:

Building Blocks for a European Organ-on-Chip Roadmap

Appendices

Appendix A: White paper on Standardization

Executive Summary
Standardization is a method to provide guidance in a particular industry. It has a persistent and often ambiguous influence on innovation. Standardization efforts are very different for industries in different stages of development. The Organ-on-Chip (OoC) community can find a basis for standardization in standards already developed in areas of individual components such as sensors, microfluidics and cell cultures. This document aims to introduce the theoretical framework of the process of standardization, its functionality, and a current and future view of standardization efforts related or of importance to the OoC field.

Introduction and Overview
Standardization is the process of developing and implementing specifications based on the consensus of the views of firms, users, interest groups and governments. This process then ensures an optimum degree of order of the rules, guidelines or specifications. In this document, the definition and impact of standardization are introduced, the functions of standardization, and the methodologies to create new standards. Finally, the benefits and pitfalls of standardization in the field of OoC devices and systems are discussed. Further, already running standardization efforts are identified which address certain aspects of technology and operational processes in the OoC field.

1 Definition and impact of standardization on innovation

Standardization is the process of developing and implementing specifications based on the consensus of the views of firms, users, interest groups and governments (Sherif, 2001; Xie et al., 2016). The resulting standards are intended to promote compatibility, interoperability and quality. Standards can be developed by standard development organizations, such as the International Organization for Standardization (ISO), or independently by companies who have a dominant position in the market (Utterback and Suarez, 1993). The economic cost of inadequate or non-existing standardization in a particular industry can be very high. For example, in the automobile industry in the US, about US$ 1 billion per year is lost due to interoperability problems associated with sharing product and engineering data (Tassey et al., 1999).

To understand the functional aspects of technology standards, it is helpful to consider the differences between the supply and demand side. On the supply side, a technology standard represents the synthesis of proven concepts on the design logics to organize the hierarchy and functional parameters of a particular type of product (Narayanan and Chen, 2012; Tassey, 2000; Tushman and Anderson, 1986). On the demand side, it reflects the desire for a consumer or user for agreement on a uniform technological format that allows for integration and interchangeability across multiple end products (Axelrod et al., 1995). Thus, a technology standard represents the collective choice resulting from a balance between utility, technical possibilities and the cost structure of manufacturers on the one hand, and constraints of political, social and economic institutions on the other (Garud et al., 2002; Hargadon and Sutton, 1997; Narayanan and Chen, 2012; Tassey, 2000).

Standards played an important role in the industrial revolution as they allowed companies to achieve economies of scale and enabled markets to execute transactions in an equitable and efficient manner (Tassey, 2000). The traditional economic function of standards can restrict the product choice in exchange for the cost advantages of scale, but more advanced standards can, on the contrary, facilitate product variety and thus choice.

Although there is a large group of researchers that claims that standardization has a significant positive and accelerating effect on innovation (Hashem and Tann, 2007; Rysman and Simcoe, 2005), there are also other reports claiming that it constrains innovation by hampering creativity and delaying commercialization of inventions (Hamel, 2006; Hill and Rothaermel, 2003). As standardization affects both innovation and technology diffusion, the concern of R&D policy should be the evolutionary path by which a new technology becomes standardized. Standardization can indeed increase efficiency within a technology life cycle, but it can also prolong existing life cycles to an excessive

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degree by inhibiting investment in technological innovation that creates the next cycle (Tassey, 2000). In the following Section, we will elaborate on the functioning of standards, and how to develop them.

2 Standards functions and development methodology

2.1 Functions of standardization

Some of the basic functions of standards can be categorized in 4 groups: *quality/reliability, information standards, compatibility/interoperability, and variety reduction*. A standard that specifies a minimum level of performance often provides the point of departure for competition, which benefits the user or consumer eventually. By reducing the transaction cost between buyer and seller drastically, a range of measurement and test method standards provides information in advanced industries. For R&D processes, an efficient way of working can be obtained by standardizing the scientific and engineering data, and by using standardized equipment calibration techniques. Besides this, real-time monitoring and control of certain processes can eliminate wasted material and increase product mix flexibility (Tassey, 2000).

Standards specify properties that a product must have in order to work with complementary products within a product or service system. Compatibility or interoperability is typically manifested in the form of a standardized interface between components of a larger system. Most commonly, interface standards provide “open” systems that allows proprietary component designs to coexist. So, they enable innovation at the component level by being competitively neutral with respect to design. Competitors can innovate on either side of the interface leaving the consumer with a choice to select particular components to optimize the system. Standards do limit a product to a certain range or number of characteristics such as size or quality levels. The 4th function is thus the reduction of variety to attain economies of scale. This is achieved by most standards, but not only by treating particular physical dimensions of a product, but also data formats and combined physical and functional attributes.

Standardization is not an all-or-nothing proposition; it typically proceeds in an evolutionary manner. Its patterns are determined by the pace of the technology development and changes in market structure. Government can play an important role in establishing and demonstrating a backbone infrastructure, which in turn promotes private-sector R&D investment in standards to enable effective use of this infrastructure. Innovation in certain markets can be heavily impacted by regulatory instruments. Although regulation often comes with increased costs or restriction in freedom of action, well designed regulation may guide or even force firms to invest in innovative activities (Porter and van der Linde, 1995). Regulation stems primarily from a top-down approach, while formal standards are typically the result of a market-driven process, or differently put, self-regulation vs. direct governmental regulation. Moreover, regulation is mandatory, while the adoption of formal standards is voluntary. According to Blind and Mangelsdorf, in uncertain markets, the effects of formal standards and regulation in relation to regulatory capture do not differ substantially from each other (Blind and Mangelsdorf, 2016). In uncertain markets, regulators have less access to information than the standard setters, causing an information asymmetry.

2.2 Development of standards

ISO is an independent, non-governmental organization with members being the standard organizations of the 162 member countries. It is around since 1926 and is the largest developer of international standards, with over 20,000 standards been set up. Other technology standard organizations are the Institute of Electrical and Electronics (IEEE), Internet Engineering Task Force (IETF), and 3rd Generation Partnership Project (3GPP). Like a symphony, it takes a lot of people working together to develop a new standard. The role of the standard development organization is to conduct this process, while the orchestra is made up of independent technical experts[2]. These experts form then a technical committee that is responsible for a specific subject area. They begin the process by developing a draft that meets a specific market need. This is then shared for commenting and further discussion.

The voting process in the technical committee is key to achieve consensus on the standard development. If no agreement is reached, the draft will be modified further, and voted on again. In the experience of ISO, developing a standard typically takes about 3 years. Figure A1 shows the main stages in the process of ISO.

The key principles in standard development can be summarized in the following 4 items:

1. *ISO standards respond to a need in the market*
   The request to develop a new standard always comes from industry or other stakeholders. In the process, a member of the stakeholder group contacts the national member of ISO, who then contacts ISO.
2. *ISO standards are based on global expert opinion*
   ISO standards are developed by groups of experts from all over the world as part of larger groups called technical committees. These experts negotiate all aspects of the standard, including its scope, key definitions and content.
3. *ISO standards are developed through a multi-stakeholder process*
   The technical committees are made up of experts from the relevant industry but also from consumer associations, academia, NGOs and government.
4. *ISO standards are based on a consensus*
   Developing ISO standards is a consensus-based task. Comments from all stakeholders are considered.

[2] Available at: https://www.iso.org (accessed 19.03.2019).

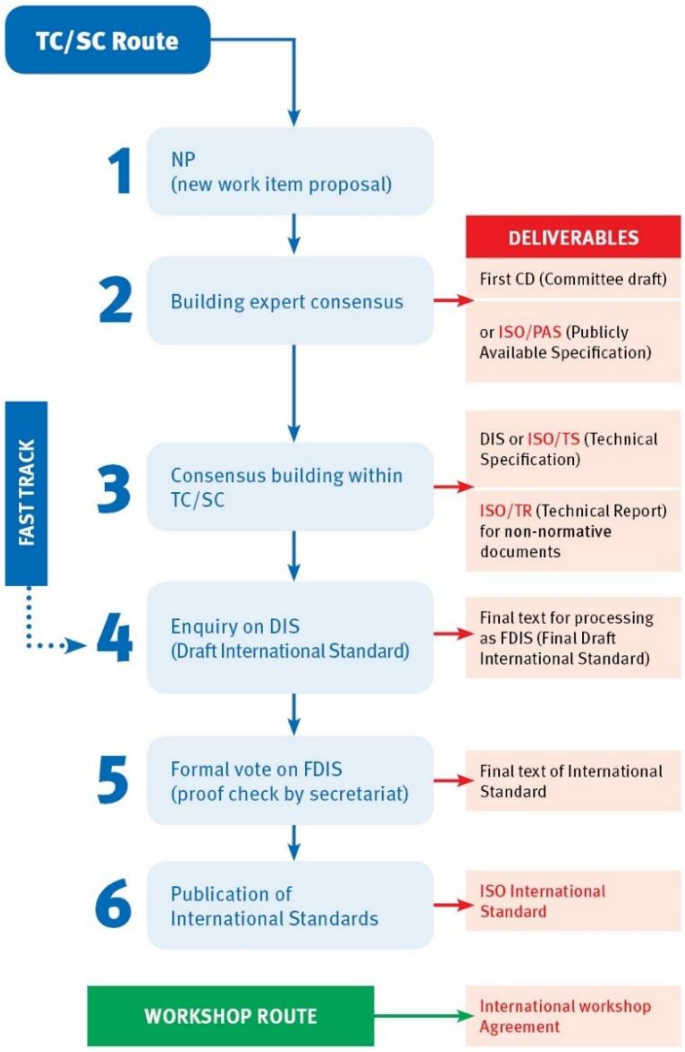

Fig. A1: ISO standards development process
(TC): a Technical Committee, which develops standards in a certain sector or industry
(SC): a Subcommittee, which addresses a specialized area within a TC

In the electronics industry, the Semiconductor Equipment and Materials International (SEMI) is an organization that provides industry stewardship and engages its members to advance the interests of the global electronics supply chain. SEMI has a standards program which is also one of their key services for the benefit of the worldwide semiconductor, photovoltaic LED, MEMS and flat panel display industries. The program started over 40 years ago in North America but was expanded in 1985 to include worldwide programs. It operates as a neutral forum for the exchange of information among suppliers and users resulting in the production of timely and technically accurate specifications and other standards of economic importance to the industry. Over 5,000 technologists representing both device manufacturers and equipment and materials suppliers participate in the program.

The SEMI standards program provides a framework and procedures for industry experts to meet, discuss, and develop essential standards and guidelines. Once the need for a standard has been identified with appropriate input from the user community, a task force is assembled to carry out the development effort. The result of this process is a draft document, which is then reworked until consensus is reached. The consensus is then reported regionally to obtain comments from other members. When that stage finishes, the worldwide balloting process is initiated to search for global consensus.

The new standard is then communicated to the industry and users are advised to cite and utilize them, although the use is entirely voluntary. Management of the program is provided by industry volunteers serving on administrative Regional Standard Committees in North America, Europe, and Japan. The international Standards Committee has the

overall responsibility for the conduct of the program. It establishes the regulations governing the program procedures and maintains relationships with other standard-setting organizations worldwide[3].

3 Standardization for lab-on-chip and organ-on-chip devices

3.1 Debate and ongoing efforts

As lab-on-chip (LoC) technology matures, there is a growing debate about standardization. As previously discussed, there are advantages and disadvantages of standardization and their impact on innovation. This has led to different views on whether standards need to be developed for microfluidic devices (Klapperich, 2009; van Heeren, 2012; Haeberle and Zengerle, 2007). Microfluidic technology is the heart of a LoC device, and also forms a crucial aspect of OoC devices.

One of the key points that hamper standardization efforts is the lack of vocabulary for microfluidics. Before reaching a standard for a product, testing standards have to be developed. Testing standards enable an objective comparison between the data sheets of competing products, independently of any specified technical requirement for the product. A variety of testing standards have been suggested already[4,5] based on the current need for methods to measure, e.g., the internal dimensions of microfluidic devices, solution temperature, electroosmotic mobility, zeta potential and autofluorescence (Stavis, 2012).

One of the key features under discussion is the standardization of interconnects, connections made to/from microfluidic devices (Fredrickson and Fan, 2004). One of the remaining issues to be solved is what aspects of interconnects should and can be standardized. A possible solution is to make a strong link between microfluidic interconnects with existing standards already found in laboratory equipment such as (mini)Luer connections to microscope slides or microtiter plates (Harink et al., 2014; van Heeren, 2012). Still, following that trajectory might lead to increasing costs. The effort of attempting to publish document standards has led to the creation of a working group in ISO, CEN/TC 332 (WG 7 micro process engineering), and subsequently the publication of a document entitled "*Micro process engineering – vocabulary*" *(ISO 10991 2009).* Additionally, there is a DIN (*Deutsches Institut für Normung*) standardization group on characterization for microreactors.

Ongoing efforts exist between stakeholders from the Microfluidics Consortium[6] and consortium partners of an EU project called MFmanufacturing[7], some national groups and SEMI. A questionnaire was sent around, and responders consisted of small-medium enterprises (SMEs) for about 50% and research laboratories (a quarter). The rest of the responders consisted of large enterprises and other research organizations. The discussion has identified several implementations of connectors in microfluidic devices and it was found that, for example, connectors should be easy to plug, be removable and reusable. Another outcome identified the need to have the microfluidic connector be easily combined with other connectors such as electrical and optical. Further, because of the growing trend of miniaturization, smaller components and thus smaller pitch spacing dimensions are needed. The MFmanufacturing project defined a specific standard pitch spacing based on a 0.75mm grid using multiples of 0.75. Another outcome of discussions among stakeholders identified the need for edge connectors and reliability (van Heeren et al., 2015). From the need of reliability arises in turn the need to develop suitable testing schemes. A common testing strategy can also speed up the process of testing and limit duplication efforts, eventually leading to harmonization on activity on a global scale.

In a simplified view, adding of cell cultures to microfluidic lab-on-chip devices has led to the development of organ-on-chip systems. Indeed, with the advent of human stem cell-based cell cultures, study and testing of human physiology and pathophysiology in a dish has become reality. A key challenge, though, is the quality control and lack of standards in cell culture in terms of, e.g., protocols and reference cell lines. Besides the cells themselves, *in vitro* culture conditions also need standardization: culture medium, medium conditions, frequency of replenishment. Operations linked to cell culture include cell culture handling and maintenance, antibiotics use, and are also of great importance in the process of standardization.

The International Society for Stem Cell Research (ISSCR) has historically developed guidelines that address the international diversity of cultural, political, legal, and ethical perspectives related to stem cell research and its translation to medicine. The guidelines were updated in 2016 to encompass a broad and expansive scope of research and clinical endeavor, imposing rigor on all stages of the research, addressing the costs of regenerative medicine products, and highlighting the need for accurate and effective public communication[8]. However, standardization is implemented to a very limited degree so far, especially in the field of induced pluripotent stem (iPS) cells, which is strongly linked to the OoC technology.

[3] Available at: http://www1.semi.org/en/Standards/P_000787 (accessed 19.03.2019)
[4] iNEMI Technology Roadmap, MEMS Technology Working Chapter 2011.
[5] SEMI International Standards, Technical Committee Charter, Charter of Global MEMS/NEMS Committee.
[6] Available at: http://www.microfluidicsinfo.com/ (accessed 19.03.2019).
[7] Available at: http://mf-manufacturing.eu/ (accessed 19.03.2019).
[8] ISSCR Guidelines for Stem Cell Research and Clinical Translation: https://bit.ly/2TO2eUu

3.2 Steps towards harmonization

For LoC devices, and more in particular microfluidic chips, a first step towards harmonization is the development of a generic classification system which is independent of the application. One potential way to do this is by classifying microfluidic devices according to certain similarities, for example according to the temperature and pressure under which they have to operate. A recent example of a path towards standardization of microfluidics was presented by Dekker et al., where a modular toolbox of microfluidic components was demonstrated, and which standardization effort was backed up by the MFmanufacturing consortium (Dekker et al., 2018). A combination of microfluidic building blocks (MFBB) and fluidic circuit boards (FCB) designed and fabricated according to guidelines which have been documented in an ISO workshop agreement[9]. Interoperability is key to make this concept work. Therefore, the outside dimensions are standardized according to a grid. A library of CAD based designs is available for any designer to develop specific devices with unique physical dimensions, while decoupling this from the functional design. This approach is very similar to methods used in the electronics industry.

In the field of cell culture-based systems, harmonization was found by a group of stakeholders seeking a set of specialized standards to ensure quality in cell culture-based systems and tools. The recently approved OECD Guidance Document on Good In Vitro Method Practices (GIVIMP)[10], coordinated by the European Commission Joint Research Centre's EU Reference Laboratory for alternatives to animal testing (EURL ECVAM), provides a framework of technical and quality practices to help ensure that the overall development and implementation of *in vitro* methods is of scientific integrity and of the highest quality possible. While the guidance is intended for all OECD member states and encompasses a wide range of audiences including method developers, validation bodies and end users, its greatest impact may be in regions where *in vitro* methods are just beginning to take root. GIVIMP tackles the following key aspects related to *in vitro* work: (1) Roles and responsibilities, (2) Quality considerations, (3) Facilities (4) Apparatus, material and reagents, (5) Test systems, (6) Test and reference/control items, (7) Standard operating procedures (SOPs), (8) Performance of the method, (9) Reporting of results, (10) Storage and retention of records and materials. The document identified quality requirements for equipment, material and reagents (e.g., cell line authentication, cell purity, stability and functional integrity, testing for microbial contaminations, use of serum, alternatives to the use of animal sourced serum, antibiotics, special media, certificate of analysis, stability and traceability). Within GIVIMP, there are relevant annexes such as the Good Cell Culture Practice (GCCP), established to reduce the risk of generating erroneous data as well as worker health issues and legal liabilities (Coecke et al., 2005), the Good Cell Culture Practice for stem cells and stem-cell-derived models (Pamies et al., 2017), and mentions to standardization and accreditation bodies as well as to Good Laboratory Practice (GLP).

3.3 Standardization for the OoC field

The OoC field is a young but fast developing field. The industry today is consisting mainly of start-ups and many developments are still in a research phase. However, individual technology and biology components and operational processes of the OoC systems have been around much longer, and standardization efforts can be found (see above; microfluidics). The challenge for the OoC field will be integrating these components and adapt existing standards to the more complex nature of the OoC technology. Ongoing harmonization in the field of microfluidics and cell culture, and existing standards in the electronics industry can represent a strong base for guidelines in the OoC field[7,8]. Moreover, efforts initiated by regulatory stakeholders, industry and academic labs by a need for novel regulation, such as novel ICH (E14, S7B) guidelines for cardiotoxicity as presented by the CIPA initiative[11], can possibly overcome the challenges that are related to an immature and uncertain market (see above), and drive standardization in the field.

The electronics industry follows strict roadmaps in terms of technology nodes, packaging, handling, etc. OoC systems can benefit from these standardization efforts by adopting those standards (see IEEE, SEMI) for the development of new sensor/actuator technology. Currently, there is a myriad of sensor implementations, few of which are based on standardized fabrication flows. Interaction with stakeholders or technical experts in the SEMI organization represents an opportunity for OoC developers to seek harmonization.

Regarding standardization of cell cultures and operations related to them, OoC systems can build readily on efforts already developed by the toxicology and stem cell research community, and which are embedded in the OECD guidance document GIVIMP, GCCP documentation and ISSCR guidelines[7]. Specific guidelines related to OoC systems are already described in the GCCP document, and challenges for the OoC field are defined as: (1) the lack of detailed understanding of some human organs and tissues, (2) complexity of protocols, (3) expensive technologies, (4) requirement of precise cellular manipulation, (5) reproducibility of the systems. Further, there are also training/education guidelines described in the GCCP document: iPSC differentiation protocols, co-culture of differentiated cells, the use of microfluidics in combination with cells are the main challenges (Pamies and Hartung, 2017).

[9] IWA 23, Interoperability of Microfluidic Devices – Guidelines for Pitch Spacing Dimensions and Initial Device Classification, 2016
[10] *Guidance Document on Good In Vitro Method Practices (GIVIMP)*, OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris. doi:10.1787/20777876 (accessed 27.03.2019).
[11] https://cipaproject.org/

In analogy to many existing overarching organizations in different fields of research and development driving standardization efforts, the newly founded European Organ-on-Chip Society (EUROoCS)[12] can play a role in mediating and facilitating standards in the field of OoC by bringing together stakeholders of industry, regulators, academia, clinicians and patient organizations. Thereby it will be important to keep its actions open to the international OoC community and search for international harmonization of guidelines.

To move OoC technology towards standardization, the OoC community (stakeholders, national and international societies) needs to get organized to reach a common goal. Regular meetings between Key Opinion Leaders (KOL) from industry, regulatory bodies, academia, clinics, and patient organizations should be organized to discuss standardization in detail. This working group can then disseminate the outcome of the meetings, i.e., report on the discussion points and if possible, formulate guidelines.

Standardization can be a step towards open technology platforms, as criteria defined in the guidelines can result in common design environments and building blocks (cfr. Microfluidics). As described above in the theoretical framework and from learnings of other industries (such as the automobile), the earlier efforts are taken up for standardization, the easier implementation will be. Further, this would also translate in a more efficient spending of available development costs, and thus have a distinct influence on the level of maturity of the field.

Within EUROoCS, a standardization workgroup/committee, consisting of KOL's of different stakeholder groups, can take up the role to drive standardization effort. The committee could meet on a regular basis to identify standardization needs and could invite relevant stakeholders from academics, industry or regulatory bodies to aid the process.

Conclusion

Standardization in relatively new industries can be driven by government, a changing regulatory landscape or a dominant player. The young OoC field is defined by several small companies and a growing academic crowd. Pharmaceutical industry as end users and regulatory bodies are closely involved in several initiatives. OoC technologies, however, can build upon established standardization efforts related to its subcomponents such as microfluidics and stem cell technology. Finally, a leading role in terms of standardization could be taken up by the EUROoCS consortium, considering international initiatives, so that guidelines are harmonized on a global scale.

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Appendix B: The ORCHID Strategy workshop: The experts

The experts that participated in the ORCHID Strategy workshop (Leiden, The Netherlands, 17th January 2019) are[13] (in alphabetical order):
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