Future needs for CRO

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Ronald Tse

Recommendation L describes the “International Model” for reducing trade barriers and facilitating market access

L **International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice[1]**

Annex A of Rec. L describes CRAs that applies generally

Annex A

Principal elements for regulatory harmonization based on good regulatory practice in regulatory fields and accompanying trade and industry sectors.

The principal issues to be addressed by interested regulators in a Common Regulatory Arrangement (CRA) document, would include:

- Legitimate regulatory objectives that usually relate to public health, safety or environmental protection, etc.;
- Applicable international standards that contain requirements for systems, processes, products and services;
- Ways of assuring and demonstrating compliance with the regulatory objectives;
- Provisions on third-party-assessment bodies, when recourse to third party assessment is needed;
- Provisions for post-market surveillance.

But CRA requirements in Annex A are product-focused

1. Scope statement

A statement of the products or product areas that are covered by the CRA.

Regulators should agree on the products for which legitimate regulatory objectives are required. For this purpose regulators may use international classification schemes such as the harmonized commodity description and coding system.

2. Product requirements

Legitimate regulatory objectives reflect the requirements to protect public interest in areas such as human health or safety, animal or plant life or health or the environment. The requirements needed for protection of legitimate objectives should lay down the principal issues of concern and be specified in terms of performance requirements rather than design or descriptive characteristics. Requirements should be limited to relevant aspects and be proportionate to the hazard inherent in a given product or product area.

3. Reference to standards clause

The CRA should contain a list of applicable international standards that correspond as a whole or partially to the requirements.

The CRA may contain a provision that products complying with the referenced international standards are presumed to comply with the requirements.

4. Compliance clause

The CRA should contain a provision on how compliance is demonstrated.

Regulators should agree on the range and contents of possible conformity assessment procedures that are considered to give the necessary level of protection under the CRA. The CRA should also specify the conditions under which suppliers can make a choice if more than one option is provided for. Such options are, for instance, supplier's declaration of conformity, third party certification or inspection.

In considering such options regulators should aim to avoid duplicative conformity assessment testing and certification for products (and replacement parts that are included in the product certification) that add unnecessary costs and time delays.

5. Market surveillance clause

Regulators having agreed on CRA are responsible for market surveillance on their territory and have the right to withdraw products from their markets if these are not in compliance with the CRA.

The CRA should contain a provision (protection clause) that if products claiming conformity with the CRA that do not conform to its requirements, the regulator may, with the intention to preserve legitimate objectives, withdraw such a product from its market. Furthermore, the CRA should contain a provision that the regulator using the Protection Clause should state specifically what products have been removed from the market and what requirements of the CRA have been claimed to be met but have not been met.

In a case where products are in conformity with the CRA or the applicable international standard but are still found to endanger legitimate objectives, the regulator having agreed on a CRA could withdraw such products from the market or restrict free circulation. In this case, the use of the Protection Clause should also be subject to the condition that the regulator using it should indicate the reasons for this decision.

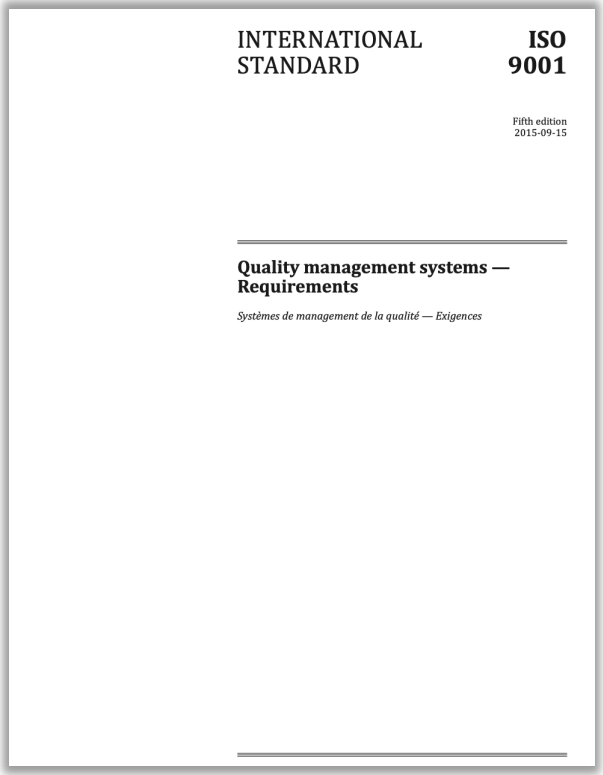
Servitization started in the late 1980's

- Servitization: shifted focus from product towards services
  - Vandermerve and Rada 1988
- In 2001, the services revenue of IBM surpassed hardware revenue
- 63% of the Fortune 100 companies already operate as solution sellers
  - Booz Allen Hamilton
- The product is no longer the prime factor in the exchange of goods
  - Vargo and Lusch, 2004
- Moving from a goods-dominant to a service- dominant direction
  - Lusch, Vargo and Wessels, 2008
- Focus of CROs should also change

How do we change Rec L?

- International standards have also gone through a process to service migration

- ISO 9001:2005 was product focused
- ISO 9001:2015 generalized “product” to “product and services”.


INTERNATIONAL STANDARD

ISO 9001

Fifth edition
2015-09-15

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

ISO 17065 on conformity assessment

- “Conformity assessment — Requirements for bodies certifying products, processes and services”
- Requirements for certification bodies
- Generalized to handle
  - certification of processes
  - certification of services

Annex B
(informative)

Application of this International Standard for processes and services

B.1 Explanations of how to apply this International Standard to the certification of processes

When applying this International Standard to the certification of processes:

— replace “product(s)” with “process(es)”;

— replace “production” with “operation”;

— replace “produced” with “operated”;

— replace “producing” with “operating”.

B.2 Explanations of how to apply this International Standard to the certification of services

When applying this International Standard to the certification of services:

— replace “product(s)” with “service(s)”;

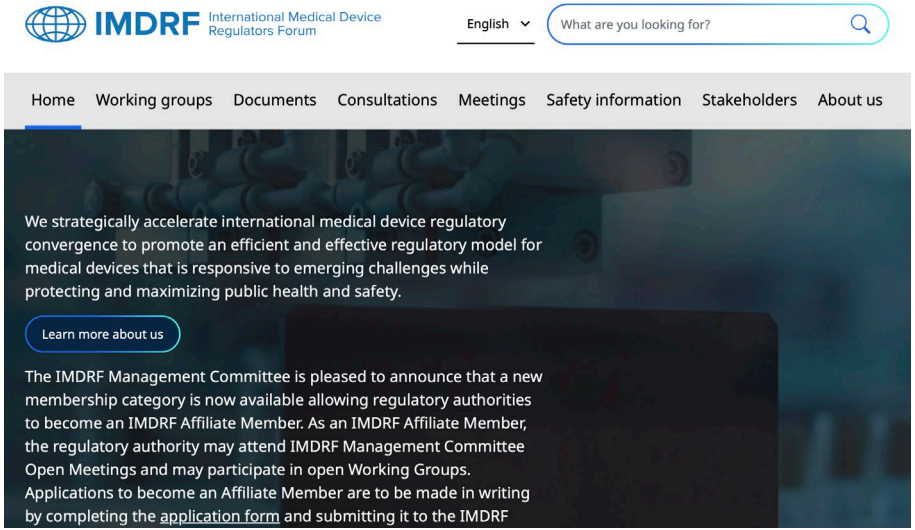
— replace “production” with “provision”;

— replace “produced” with “provided”;

— replace “producing” with “providing”.

Successful industry-led example: medical devices

- Requirements for medical devices manufacturers
- International Medical Device Regulators Forum (IMDRF)
- ISO 13485, ISO 14971
- Working with multiple regulatory authorities to establish the Medical Device Single Audit Program (MDSAP) scheme



Other possibilities for CRAs

- Not an extension of the International Model, but a faithful alignment to original scope
  - Services
  - Processes
- Many possibilities in terms of regulatory harmonization:
  - Sustainability processes, products, services
  - Advanced manufacturing processes
  - AI certifications