Strategy for IVD product development, validation and commercialization

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SME based in Lyon (FRANCE)
- Spin-off of from CNRS-University Lyon 1
- Founded in 2010
- Headquarters and production unit in clean room

Multiplexed diagnostic solutions
- Patent: HIFI Technology
- Applications:
  - Rare blood group genotyping (CE-IVD)
  - Allergy diagnosis
  - Bladder cancer biomarker detection
  - Identification and characterization of pathogens
  - Biologic traces detection for forensic
Position of the company

- 50 % of the activity is about R&D and product development
- All the commercial profits are re-invested in R&D

R&D project status:
- 2 projects led to commercial products:
- 3 are ongoing development project
- 2 in standby

HIFI Blood 96™
Since 2012
WHO stated that

- Antibiotic resistance is one of the biggest threats to global health today. It can affect anyone, of any age, in any country.
- Antibiotic resistance occurs naturally, but misuse of antibiotics in humans and animals is drastically accelerating the process.
- A growing number of infections are becoming harder to treat as the antibiotics used to treat them become less effective.
- Antibiotic resistance leads to longer hospital stays, higher medical costs and increased mortality.

World bank stated that Microbial resistance will

- Lead to a global economical threat comparable to 2008 financial crisis
- Increase poverty, especially in poor countries pushing more than 28 millions people in poverty towards 2050

There is an urgent need to detect, screen and monitor resistances factors, from the very begining of the patient care strategy.
The Scientific and Technological Context

Today a huge knowledge regarding pathogens characteristics is available

- Coming from Sequencing
- Stored in rich genome databases

- How to take advantage of this knowledge to tackle down the resistant pathogen threats?
FAPIC project

Automated Interpretation (Software)
Steps of product development

- **Development** (ISO 13485 Standard designated as EN ISO 13485:2003 is seen as the *de facto* standard for the medical device industry.
  - Proof of concept
  - Optimization
  - Validation of instrumentations (great task, which is getting more importance including all embedded *electronic* and *software*)

- **Produce Prototype batches**
  - Performances evaluation
  - **Performance validation** (crucial step, has to be done in close relation with marketing/customer requirement) compliant with the norms.
  - Procedure for validation of raw materials, procedure for validation of batch production
  - Industrialization transfer file
  - Routine production (from this step only minor changes in the product are allowed)
  - Commercialization
  - Customer feedback (improvement)
Steps for Performances evaluation:

- Declare the performances
- Write a plan of evaluation
- Perform studies of performance evaluations
- Validate the performance evaluations
- Modify/adjust performance evaluation during the process, if necessary

Performances can be validated and claimed
Particularity of multiplexing, regarding performances and QC

- Multiplexing provides many results, which are somehow related, they’re never independant.

- The multiplex particularity is not detailed in the CE directive, DIRECTIVE 98/79/CE. (« the performances »)

- Two challenges appear:

  - **Performances:**
    - Performance of a single parameter, within a chip / regarding other parameters?
    - How to claim performances? Globally for the chip, individually for each parameters, or both?

  - **Quality controls from batches:**
    - Considering that the assay is destructive for the device:
    - how many tests should I run?
    - -consider the prevalence
Regulatory Requirements

IVD Medical device:

Directive 98/79/EC In Vitro Diagnostics Medical Device Directive

- **Software** is crucial in innovatives IVD devices.

- Interpretation software **standard (EN 62304) Medical device software — Software life cycle processes**

- This standard defines the life cycle requirements for MEDICAL DEVICE SOFTWARE. The set of PROCESSES, ACTIVITIES, and TASKS described in this standard establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.

- The acceptance criteria of the products have to be precisely defined and documented.

- **Quality Controls for batch releases:**
  - **ISO 2859-1:1999(en)**

  - Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

  - This part of ISO 2859 specifies an acceptance sampling system for inspection by attributes. It is indexed in terms of the acceptance quality limit (AQL).
CE-IVD products

New Classification

- The new EU regulatory framework for in vitro diagnostic (IVD) medical devices will soon replace the Directive 98/79/CE (with a transition period of 3-5 years).
- There will no longer be a list-based classification of IVD devices but a division into risks classes (classes A – low risk to D – high public and high patient risk).
- There are seven classification rules according to the purposes of the medical devices:
Thanks!

Question?