Introducing the HORIBA Medical's Response to a Highly Evolutive Laboratory's Market.

HELO: the Horiba Evolutive Laboratory Organization

Laurent ARAUD

Olivier POU

Over the past 5 years, HORIBA Medical has been proposing the "HaemCell" as the high-range solution for Hematology Laboratory organization which was based on software connections only and avoiding any mechanical link. To improve patient care and adapt to a highly evolving market, HORIBA Medical decided to make the HaemCell evolve toward the HELO concept and exploit at their best the analyzer's performances and scalability for healthcare needs. Still driven by the LEAN philosophy the new HELO concept extends the flexibility of configuration by adding the possibility to work with a track system and offers around both the work-cell and the dedicated track a multiplicity of peripheral solutions to accommodate modern requirements of the Hematology laboratory as well as related disciplines.

Introduction

The first HORIBA Medical laboratory organization step, called "HaemCell", was designed around the Hematology Expert data manager software (the Pentra ML) which was able to communicate with only HORIBA Medical Hematology products range and no other competitive Hematology instrument nor to any other disciplines present in the laboratory. This first step in laboratory organization helped optimize Hematology production but limited the benefits to the Hematology only. Despite its LEAN benefits, the Workcell configuration put forward in the HaemCell did not address all types of laboratories and with a significant part of the market remaining attracted by a Hematology chain/track organization, it became necessary to consider providing both options for maximum flexibility. Additionally, to improve diagnostic testing quality and thus patient care, laboratories need to consolidate data from various disciplines and more and more from different geographical sites. HORIBA Medical therefore decided to develop a new concept which extends the perimeter of inter-connectivity beyond the Hematology department through flexible peri-analytical solutions able to work in both workcell and track system environments but also linking other disciplines, other sites and other Laboratory Information Systems.

A Market in deep mutation

The Worldwide IVD (In Vitro Diagnostic) market (Table 1) represented 54.5 billion $ in 2013 which represented a 4.1% growth compared to 2012. The Hematology

Table 1 IVD Market by disciplines (2013).

Test Discipline	Sales $-million	% growth 2012-2013
Central Lab Immunoassays	$13,188	5.9%
Whole Blood Glucose Monitoring	$8,424	–3.9%
Central Lab Clinical Chemistry	$6,691	4.2%
POC/POL	$5,600	7.0%
Clinical Molecular	$4,161	7.9%
Microbiology	$2,836	4.8%
Anatomic Pathology	$2,676	6.2%
Hematology	$2,602	6.3%
Coagulation	$1,625	4.9%
Immuno-Hematology	$1,510	3.0%
Blood Screening Immunoassays	$1,359	4.3%
Blood Screening Molecular	$785	3.9%
Central Lab Critical Care	$737	4.3%
Clinical Flow Cytometry	$678	5.3%
Central Lab Urinalysis	$500	5.4%
Other Products	$1,130	5.0%
TOTAL	$54,502	4.1%

Source: Enterprise Analysis Corporation 2014

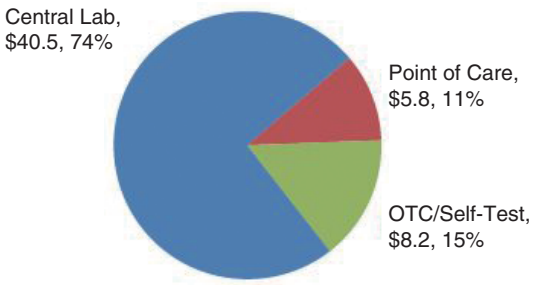

Figure 1 IVD Market (2013).
Source: Enterprise Analysis Corporation 2014

market which is estimated at 2.6 Billion $ in 2013 grew over the same period by 6% while the clinical chemistry market grew by 4% to 6.7 billion $. Hematology market has thus experienced one of the strongest growths in 2013 compared to other disciplines. The IVD market split per region showed domination by the North American and EMEA (Europe, Middle East and Africa) region: North America (43%), EMEA (35%), Asia/Pacific (11%), Japan (7%) and Latin America (4%). In 2013, the great majority of the IVD activity (Refer to Figure 1) is found in the central laboratories (40 billion $, 74%), while POCT (Point of Care Testing) represents only 5.8 billion $ (11% but with a high growth rate). The total IVD market is expected to grow from 2013 to 2018 at a CAGR[*1] of 4.9% to reach an estimated 69.3 billion $. However, this growth will not be a steady organic one but will surely witness major changes. The main one, initiated a decade ago in Japan and in some European countries and now spreading across the globe is the consolidation of laboratories due to economic (decrease in reimbursement and related needs for economies of scale) and regulatory (accreditation) pressures. Indeed the level of quality required by accreditation leads to consolidation of small laboratories who individually cannot afford the necessary heavy investments. This consolidation impacts mainly the Private market but may affect to a lesser extent the public healthcare system too.

Some European private laboratory markets are still extremely segmented. While in Germany, Spain and Belgium the private laboratory market is already at an advanced industrial level, the laboratory consolidation in France and in other European countries was until recently far from reaching the same development level. In those countries, the laboratory market remains closer to smaller scale production level rather than industrial level. Aside from the consolidation, another emerging factor is configuration flexibility in subcontracting by public hospitals to Private laboratories. Here again Laboratories are facing a situation which is becoming a standard practice throughout Europe. Quite developed on the British, German and Spanish markets it is not yet significant in France where only some small hospitals are beginning to sign contracts with private laboratories.

*1: CAGR: Compound Annual Growth rate is a business and investing specific term for the geometric progression ratio that provides a constant rate of return over the time period

Impacts on the Hematology laboratory

Even if the market is evolving, some of the traditional Hematology laboratory requirements remain valid. Currently, Hematology laboratories share common requirements with general core laboratories (grouping all disciplines) such as a high level of quality assurance and an adaptable productivity with an optimized TAT[*2] for routine samples and for urgent samples (or STAT[*3] samples). In any circumstances, laboratories need a flexible solution able to absorb the daily fluctuation of activity while TAT's objectives must be respected.

The second important requirement often relayed by laboratories is the workload flexibility for configuration. The proposed solution must match the workload and workflow of the current environment but has to remain valid (or very easily upgradable) for the next 5 or 6 years (a standard timeframe for an IVD contract). This becomes an even more important requirement in countries like United Kingdom where the public sector starts to impose on Hematology and other IVD manufacturer contracts for much longer periods of time (sometimes reaching 14 to 15 years). The capability to handle the evolution of the Laboratory for 15 years is therefore a must. However, laboratory activity tends to increase at a non-linear rate due to the laboratories' grouping or the purchasing of smaller laboratories. It thus becomes difficult to foresee their purchase opportunities 5 years ahead. They however need to have the flexibility to add, to remove, or to change their instruments following their level of activity without stopping their routine and without introducing totally different solutions which would require additional training, eventually staff and other associated costs.

Hematology differentiates itself compared to the rest of the laboratory IVD disciplines. The main specificity of Hematology laboratories compared to other disciplines is the necessity for several actions on the sample flow between the sample arrival and the result validation. Figure 2 shows specific constraints of Hematology compared with other disciplines. In the Pre-Analytical phase, EDTA[*4] tubes do not need pre-treatment such as in Biochemistry or Immunology (No aliquoting, no centrifugation, no uncapping...) and therefore it isn't as

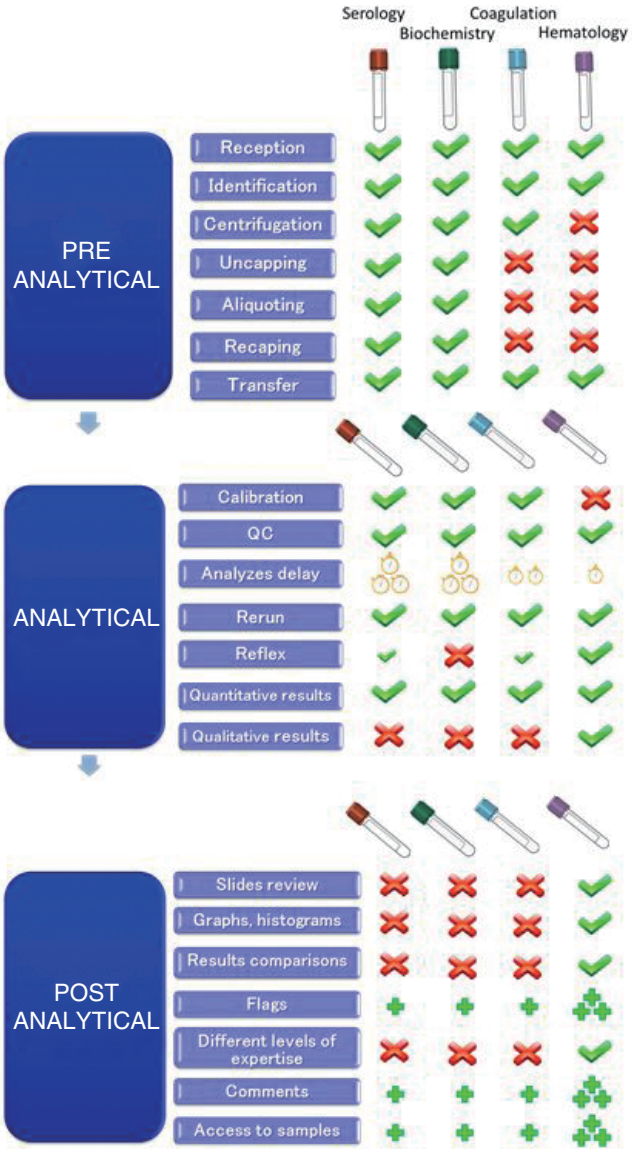

Figure 2 Specific constraint by discipline.

critical as it can be for the other disciplines. Then, in the Analytical phase, EDTA tubes require specific tasks (Reruns, reflex additional tests, reflex slides, slide review in the case of flags) and therefore time. Finally, in the Post-Analytical phase, the other discipline's tubes are validated quite quickly while hematology samples require human intervention and expertise in result interpretation.

*2: TAT: Turn Around Time, Delay between the tube arrival in the lab and its results validation (sent to the Laboratory Information System)

*3: STAT: Short Turn Around Time samples. It means urgent samples requiring a short TAT.

*4: EDTA: Ethylene Diamine Tetra Acetic Acid. It is an anticoagulant for blood samples.

The HELO response

H.E.L.O. stands for HORIBA Evolutive Laboratory Organization. It takes into account the Hematology specificities mentioned earlier and provides the necessary flexibility and scalability required by the laboratory environment evolution. The HELO concept gathers the tools, instruments and services which allow the analysis of the sample workflow, the simulation of the laboratory architecture and the ability to propose the most adapted and flexible configuration in accordance with laboratory requirements for the pre-analytical, analytical and post-analytical phases. Figure 3 describes the HELO perimeter.

The first HELO tool is then a "laboratory simulation software" able to analyze the samples workflow in place in laboratories and propose optimizations through the various HORIBA Medical HELO configurations. It helps laboratories to identify the presence of bottlenecks, to calculate their current and future TAT, to relate the staff presence with the necessary FTE (Full Time Equivalent) and to estimate the workload per instrument and per person. This simulation is as important at the start of the organization as it is along the way and when changes are required to accommodate evolutions presented earlier. Laboratory consolidation makes organization forecast difficult for the laboratory managers. Thanks to this tool however, a video simulation helps apprehending a typical workday including when the samples arrive, the pre analytical tasks, the loading of samples loading into instruments, the reagent loading and unloading, as well as all the steps until the results are validated. It becomes possible to compare the performance of the existing setting with the proposed HELO configuration.

Figure 3 HELO concept perimeter

The workflow's video simulation is completed by "3D laboratory design" software. Based on real pictures of the laboratory site, this software is able to build 3D movie of the site. All the instruments are placed at their recommended location to ensure optimum laboratory workflow and to limit useless movement of people and samples. It also helps the laboratory manager estimate future organization in terms of space, architecture and ease of work while keeping in mind the possible future increase of the activity.

In the pre-analytical phase, the HELO concept facilitates the sample acknowledgement by checking automatically when samples arrive at the customer site and by informing the collecting site that samples have been properly received (quantity and time between both sites need to be monitored). This is done through the HORIBA Medical Middleware. It is more frequent to find an analytical laboratory working with plenty of collecting sites which makes the sample acknowledgement a tedious task for technicians.

Thanks to the HELO pre-analytical sorter, racks of tubes are loaded and then sorted according to the work list which is downloaded in real time from the LIS (Laboratory Informatics System). The HELO Middleware is the interface between the LIS and the HELO sorter. This sorter is able to work in a stand-alone organization called a "work-cell" or directly connected to a conveyor (commonly called a "track system" or "Chain system"). An optional bulk module enables technician to input tubes in bulk into the sorter that will automatically place tubes into the dedicated racks.

The HELO concept includes a wide panel of Clinical Chemistry and Hematology analytical instruments (possibly completed by a slide maker & stainer) to address small and big laboratories alike. Thanks to its Middleware, the HELO concept is compatible with almost all the instruments from the IVD market and so connects with other disciplines. From small satellite sites equipped with low range products to large hospital sites with high range products, the HELO concept is able to flexibly accommodate all expected throughput and related needs.

The HELO concept integrates a cell digitalizer able to complete an automated pre-cell classification that can be conveniently used remotely. This remote access provides a perfect environment for university teaching hospitals but also to laboratory clinicians of private groups of laboratories that often need to validate results of another site. It is able to recognize cells on slides coming from the slide maker/stainer. All the results are then directly sent to the HELO Middleware and thus to the LIS.

In order to optimize the layout, the pre-analytical sorter is also used as a post-analytical sorter and archiver. Once the blood count production is completed, all the tubes come to the sorter (manually with a workcell organization or automatically with a conveyor organization) and the Middleware informs the sorter of the remaining post-Hematology tests remaining to be done on the tubes. Those include for example the sedimentation rate or an HbA1c analysis. When all the post-Hematology tests are done, all the tubes are archived in the post-analytical sorting/archiving unit. It has the flexibility to add an optional refrigeration to the main unit to store tubes at a "refrigerated temperature". It allows the laboratory to run tests during a longer period of time after blood collection.

Once all the tests are done, laboratory technicians and physicians validate the results from the Middleware which is the heart of the HELO organization. It has a "multi-disciplines" approach. Technicians and physicians can check in real time all the present and past results (saved in a shared database) coming from all the connected disciplines. It is then possible to validate Hematology results taking into account data coming from other disciplines and to validate the patient file once all disciplines are performed.

The HORIBA Medical Middleware has also the capacity to handle "multi-sites". Figure 4 highlights the main functions of the HELO concept. For all disciplines, the Middleware keeps the memory of the patient history and demographic data from laboratory sites belonging to the same group and sharing the same network. This feature,

Figure 4 HELO main functions

already possible in the Haemcell concept, becomes a standard setting in the HELO concept. It will enable Hematology staff to work more as a "laboratory team" than before thanks to the permanent connection. Even if patients go to different sites, all the physicians in these sites may benefit from the same and best level of information. This Middleware therefore facilitates quality health care access for patients. Another advantage for the laboratory staff is the ability to work with a remote access. As laboratory technicians are connected with physicians, TAT is considerably optimized and patients enjoy faster results including days off and at night even from a remote satellite laboratory. The ongoing consolidation will inevitably create medical laboratory wasteland areas but those shall be mitigated by tools such as the remote access between satellite collecting sites and the core analytical site.

At last, the HELO concept enables U, L, I or O shape configurations on both track systems and work-cell settings. Such flexibility has so far not been possible since all chain solutions available to date on the market only propose the I shape and thus oblige laboratories to physically adapt to a rigid configuration while HELO reverses this situation and enables the proposed configuration, even with a chain, to adapt to the laboratory's needs and physical constraints, avoiding unnecessary room modification and related costs.

Conclusions

The ongoing mutation of the IVD laboratory market and consequently the evolution of the Hematology market environment are dictated by two basic and recurrent targets: provide a better service (comprehensive, with quality and fast TAT) for patient's healthcare at a more affordable cost for reimbursement systems. These policies naturally lead laboratories to seek LEAN solutions in order to improve their production while consuming a minimum amount of resources. The resulting laboratories consolidation is still heterogeneous around the world. Nevertheless the current status of the most advanced countries helps us foresee the progress of organizational future. The consolidation's pace might accelerate with national and international investors as well as hedge funds that are attracted by the changes in the IVD Laboratory business model. In parallel, the increasing consolidation is likely to lead to an increase of public/private partnerships. Indeed, with superior investment capacity, private laboratory groups will be in a better position to provide cost effective subcontracting of IVD tests to Public hospitals. Today's laboratory managers and owners cannot ignore those mutations and must seek upgradable solutions. The HELO concept has been designed to provide seem-less solutions during these structural market change.

Laurent ARAUD
Data Management Corporate Product Manager
HORIBA ABX SAS

Olivier POU
Junior Director
Distributor Network
HORIBA ABX SAS