The clinical histopathology market has developed into a highly complex branch of laboratory medicine utilizing traditional processing and sections equipment as well as immunocytochemical techniques, molecular/cellular pathology technology and virtual (telepathology) technology.

The diversification of this previously rather homogeneous market into a number of defined sub-segments requires a flexible product and distribution policy focusing on the specific needs of the users of laboratory equipment as well as the needs of purchasing agents and laboratory managers in hospitals. These needs differ in nature today and will continue to differ in the future.

Cost pressure from managed care and national health services, together with new, more stringent rules for performing laboratory tests and ongoing market consolidation among providers and many smaller companies have all made and will continue to make the histopathology industry one of the most turbulent healthcare market segments (clinical labs, hospitals, etc.). Cancellation has reduced profits and forced hospitals and privately owned labs to join integrated healthcare delivery networks, resulting in a tremendous loss of autonomy. Cost pressure plays a major role in defining histopathology testing in every major industrial country. When the caseload increases due to an ageing population and larger diagnostic panels (H&E, special stains, IHC, FISH) with a limited number of staff and need for faster patient turn-arounds, the result is a greater workload for the histology staff.

One of the prime examples for the change in the histopathology marketplace is the trend toward using fully automated (motorised) microtomes, instead of the manual equipment used previously, in order to overcome costly problems with cumulative trauma disorders (RMD’s) and loss of working hours associated with these. Another good example is the customer’s preference for total laboratory automation associated with the purchase of instruments and systems offering modern technology well balanced with performance and acceptable lifetime costs. On the purchasing side there is a definite move toward group purchasing. Furthermore, the lifetime cost of an instrument or system, technical service costs, warranty terms and financial options (lease to buy, payment per use...) all play an ever greater role in the decision to purchase.

Cost savings are causing purchasing power to shift away from the laboratory director to economic decision-makers, such as administrative and clinical laboratory managers as well as to the purchasing managers in hospitals and private laboratories.

Market trends in histopathology - demonstrated by changes in demand for microtomy

Continuous analysis of the clinical histopathology market over the last two decades has provided the suppliers of instruments and systems to this market with a good insight into the scale and dynamics of transformations in customer behaviour in this market segment.

For the purpose of this article I would like to use the change in use of microtomes to demonstrate how the altered behaviour has impacted and still impacts the entire market.

Over the past ten years it has been well documented that the number of microtomes sold to clinical histopathology laboratories is around 4,000 per year. This is approximately 85% of the total reported sales of microtomes for all known applications, including some exotic applications in the field of industrial quality control.

More than 95% of all the instruments sold every year are replacement purchases for broken or ‘aged’ instruments. Since the average lifetime of microtomes is more than 10 years, there are still some ‘historical instruments’ in daily use in laboratories across the world.

It is also well documented that in the 80’s and early 90’s the majority of the instruments sold to the histopathology community by all manufacturers combined were manually operated microtomes of the type shown in (Fig. RM 2125). Only in relation to research applications were semi-motorised microtomes (Fig. RM 2145) or even fully motorised (programmable) microtomes (Fig. RM 2165) sold to the histology market.

According to Leica studies and information exchange with other experts in the industry, the percentage volume of motorised (programmable) microtomes sold to customers in histopathology was below 5% in 1993.

Discussions in the late 80’s and early 90’s about the relevance of CTD’s and RMD’s in relation to the use of microtomes have contributed to this situation changing almost overnight (in 1990 approximately 180,000 RMD cases were reported in the United States compared to more than 300,000 cases in 1993). In 1994 and 1995 all suppliers of microtomes reported a dramatic increase in requests for motorised microtomes for use in clinical histopathology as a result of the considerable rise in the number of CTD/RMD cases reported.

Users of microtomes started at this point to recognize the most dominant sources and risk factors in the development of CTD’s and RMD’s. Apart from the already known sources - manual staining, manual covering/lipping, exchange of cassettes and blocks in microtome cassette clamps or standard microtome clamps and use of non-ergonomically designed laboratory equipment - operating manual microtomes is generally recognised as one of the most dominant causes of stress symptoms and diseases.

All these points, combined with a more affordable motorised microtome offered by all suppliers, caused the market to respond more favourably to the introduction in the late 90’s of motorised and programmable rotary microtomes. Although there are no statistical data, it is estimated that in 1998 more than 15% of all microtomes sold to customers in histopathology were motorised or semi-motorised. In 1999 the sales volume of motorised / semi-motorised microtomes of all manufacturers combined increased to above 20% (approximately 1000 units a year).

Based on customer feedback and experience gained with the RM 2155, fully motorised microtomes with ergonomic rest and ergo-control pad (Fig. RM 2153) between 1996 and 1998, Leica introduced the innovative DSC 1 rotary disc microtome for the clinical histopathology market in 1999, with the clear philosophy to promote automated microtomy to a new level. Although the instrument is still not fully accepted by some clinical histopathologists and biotechnologists owing to its novel design and futuristic outlook, the acceptance level for the instrument is increasing day by day. This third-generation system has been designed to meet and exceed today’s customers’ demands for user comfort, ergonomics, safety and sample throughput.

The Leica DSC 1 is a perfect example to illustrate how sophisticated technology can be translated into the functional tool a modern-minded microtome expert (Fig. DSC 1). The DSC 1 automated disc microtome is considered to be the first phase of ongoing research and development activities at Leica Microsystems to bring integrated workstations to the clinical histopathology laboratory.

One can speculate that the future of histopathology automation will be dominated by efforts to reduce the ‘human factor’ to a minimum. This does not mean, however, that histotechnologists will be released from their tasks, but, hopefully, that they will be provided with instruments and systems that allow them to devote themselves to more challenging duties.

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Walter Esinger, Director of International Marketing & Sales for Leica Microsystems in Nussloch, Germany, describes the changes that are transforming the environment of the modern histopathology laboratory.