Technology Transfer The Needs for Future Industrial Development

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Abstract

To date, technology transfer or exchange from accelerator laboratories to industry has been driven primarily by specialist companies who develop, manufacture and market accelerator-based equipment. The status of this market is reviewed from an end-user perspective using the medical cyclotron isotope segment of the market as an example. In general, the large accelerator laboratories are funded by central government, and are committed to supporting fundamental physics research, with only a few exceptions servicing industrial requirements. It is certain that the accelerator community now faces a watershed, with changing interests in fundamental research and a worldwide drive to privatise technology and facilities. Fortunately, there are niches of technical innovation which could lead to significant accelerator projects of commercial interest, which would lead to the creation of wealth during the next century. A possible direction for these some of these applications initiatives is discussed.

1. INTRODUCTION

The final paper in the Industry Seminar is a review of past experience and future opportunities for technology transfer between the accelerator laboratories and industry form an end-user perspective and using cyclotron isotope manufacturing as a case-study.

Amersham International, although originally an UK Government laboratory, is now an independent commercial company operating in the private sector and specialising in radioisotope and non-radioactive products for healthcare and life sciences markets on a world-wide basis. The product portfolio includes pharmaceutical grade radioisotope products manufactured using cyclotrons and all the cyclotrons have been purchased from specialized cyclotron vendors.

It is worthwhile defining the technology and the structure of this industry. Technology can be regarded as either:

- scientific or engineering information to enable 'products' to be developed, or
- completed systems or technology packages to be delivered to 'end-user' customers, or
- provision of services at existing accelerator facilities industrial operations.

The industry itself can be segmented as follows:

- 1) The laboratory or organization supplying the technology,
- 2) specialised commercial companies or 'vendors' who manufacture and supply technology packages,
- commercial companies or organizations who use the technology packages to manufacture a product or supply a service,
- 4) the customer organization purchasing the product,
- 5) the customer or real 'end-user' of the product or service e.g the patient.

It is worthwhile defining the position of each organization in this customer-supplier chain and recognizing the individual needs with regard to the flow or transfer of technology.

2. THE COMMERCIAL CYCLOTRON INDUSTRY

Currently Amersham has the largest range of commercial cyclotrons with eight machines operating at three different locations in the UK and USA. All the cyclotrons are committed to the production of radiopharmaceutical imaging products and each cyclotron was purchased from a (category 2) specialist vendor resulting in a range of different installations and ancillary systems. The chronology of this expansion in cyclotron capacity is described below:

Vendor Energy Commercial reason Project First Generation Cyclotrons UK 1963 Phillips 25 MeV Entry commercial activity USA 1972 TCC 22 MeV Entry commercial activity Second Generation Cyclotrons USA 1972 SXC 40 MeV Capacity increase and new energy for TI-201 UK 1980 TCC 42 MeV Capacity increase and new energy for Tl-201 40 MeV Capacity increase USA 1982 SCX UK 1985 SCX 40 MeV Capacity increase USA 1986 CGR 75 MeV New energy for I-123

Third Generation Cyclotrons USA 1989 IBA 30 Mev Capacity increase

First generation commercial compact cyclotrons were manufactured by companies aligned to research laboratories and both the early designs and modes of operations reflected a research laboratory philosophy. However as demand for cyclotron isotopes increased and the range of commercial isotopes was being expanded, second generation cyclotrons with improved engineered sub-systems were made available where design attention was given to reliability and maintenance.

During this thirty year period, one considerable step forward was made when IBA, at Louvain-la-Neuve, reacted to a real market demand by developing the Cyclone-30. These market requirements are:

Requirements of present-day commercial cyclotrons

High reliability operation High intensity <u>extracted</u> beam Low personnel dose exposure during maintenance Low cost operation Simple engineering design Automated controls Provision of target handling systems Efficient installation and commission and also Turnkey project management capability After-sales backup Availability of spare parts Respect of commercial confidentiality

Recently IBA have joined by EBCO Industries/TRIUMF in offering effective technology packages that meet closely the requirements of the radiopharmaceutical manufacturer.

3. MANUFACTURING PROCESS

The overall process for manufacturing cyclotron isotopes as licensed radiopharmaceuticals include the following discrete operations:-

- . production of isotopically enriched raw materials,
- fabrication of cyclotron bombardment targets,
- . cyclotron operation for target bombardment,
- . radiochemical extraction of the radioisotope,
- . waste disposal of highly radioactive waste,
- . pharmaceutical manufacturing of the final product,
- . quality control of during production stages,
- . labelling and packing operations,
- . distribution and delivery.

So, although the cyclotron operation is clearly the most capital intensive and time-critical operational component, the cyclotron bombardment represents only a small step in an extended manufacturing sequence. Experience suggests several requirements for technology transfer into this specific manufacturing area:-

- . construction and supply of the technology package should be a turnkey arrangement wherever possible posing minimal distraction to the commercial organization,
- the installed package should be reliable and predictable

in its operation,

- the subsequent cyclotron operation should not be treated as a complex physics exercise dependent on highly skilled specialists and demanding large equipment development budgets.
- . the general operation of the cyclotron should not pose a significant technical and management diversion from the primary task of manufacturing short-lived, radioactive medical products reliably.

Similar features and requirements exist for the other application segments of this industry such as PET diagnostic imaging, accelerator based therapy, electron beam sterilization etc.

4. THE PRESENT DAY COMMERCIAL ENVIRONMENT

The overall industry has common commercial demands and constraints on the implementation of accelerator technology transfer:-

a) Resources: Pure research should be sourced externally wherever possible and in-house development effort would be focused on the end-user product, the commercial company maintaining only a small development team; this is particularly relevant in the area of manufacturing technology.

b) Finance: Investment in a development project or capital equipment is usually evaluated against a company's expectation of the return on investment which reflects:-

- the risk of the project,
- . the cost of (borrowing) money,
- . the payment of shareholder's dividend etc.
- the level of retained profits for re-investment.

Therefore a commercial company's financial goal will be much greater than a nominal 'recovery of cost'.

c) Regulatory: Increasing requirements for Regulatory compliance for products and systems, particularly in healthcare manufacturing and in radiological operations, result in higher standards of reliability, reproducibility and documentation for each component stage of production.

d) Quality assurance: In modern industrial manufacturing, leading companies cite ISO 9000 accreditation for their quality assurance as a means of gaining marketing advantage. This in turn demands back-integrating this standard onto suppliers of products and services within the manufacturing chain including any aspects of technology transfer.

e) Legal: A key component of technology transfer with industry is the legal arrangement between the parties which should include:

- appropriate confidentiality arrangements
 - management of the intellectual property rights to

accommodate the wishes of both parties i.e. patents

- . agreement on terms and conditions, royalties etc.
- provision of licensing, warranties, indemnities etc.

Therefore, technology transfer requires that accelerator staff possess a range of expertise wider than just the technology and the engineering know-how.

5. FUTURE INDUSTRIAL DEVELOPMENT

Within the particle accelerator laboratory structure, programmes continue in support of particle and nuclear physics research i.e. the construction of higher energy machines, the design of more intense particle beams, hybrid collider rings etc. Society at large remains generally supportive to this Big Machine quest for fundamental knowledge, political bodies in many countries are less enthusiastic and many branches of academic research are becoming more vocal in their objections to the large costs. In effect the accelerator community is probably approaching a watershed in terms of funding and investment for larger accelerators. Interest remains high in the development of much smaller machines and in their commercial applications across a very broad spectrum with more immediate benefit to the general population, viz

- . medicine
- power generation
- . protection of the environment/waste disposal
- industrial processing etc.

Some of these future industrial requirements and opportunities are described below:-

5.1 Isotope production from higher intensity cyclotrons

The nuclear medicine industry is currently well served by commercial package offerings of 30 MeV energies and extracted proton beams in the range 350-500 microAmps. However as more first and second generation cyclotrons are withdrawn from services, many for radiological reasons, industry will need accelerators with higher intensities in the range 2000-3000 microAmps. An additional requirement, again for radiological reasons, will be higher beam quality from the accelerator to ensure that beam losses outside the target region will be < 0.5%.

It is evident that there is a further requirement for high intensity development accelerators at energies of around 100 Mev to support future exploration of new isotopes and clinical applications - an initiative is already under way with the NBTF project in the USA.

5.2 Accelerator produced neutron sources:

The radioisotope industry depends critically on material testing reactors for generating the thermal neutron fluxes in the range 0.6 to 4.0 10^{14} per cm² per sec necessary for large scale isotope production. Most of these reactors are reaching the end of their operating lifespans and are being further threatened by the uncertainties associated with the back-end problems of fuel cycle management and the eventual decommissioning costs. Coincidentally, possible neutron flux

levels generated by current and planned spallation sources are within this range, but no project has foreseen the opportunity of providing a dedicated large scale isotope irradiation station. In fact a CW spallation source with optimum energy/intensity specification could provide the isotope industry with a strategically important alternative source of materials which would be decoupled from nuclear power programmes, high level radioactive waste disposal and weapons issues.

5.3 Power Generation

Fission generated power via nuclear reactors is a highly criticised modality due to risks of criticality as well as the generation of weapons grade materials; fusion power is unlikely to be established within the next 50 years and certainly not in the form of totally 'clean energy'. The proposal for the Energy Amplifier seems an excellent first step to develop an alternative energy source which would use a raw material which is indigenous to the earth's core and which bypasses some of the major objections to present day nuclear power.

5.4 Nuclear Waste Transmutation

The legacy of 40 years of nuclear power generation and the prospect of its continuation has created a major environmental problem for which today's solutions of reprocessing and storage appear unconvincing and unimaginative. The current proposals to employ high intensity, moderately large accelerators should be pursued vigorously by the larger accelerator laboratories.

5.5 Industrial Processing and Pollution Control:

The opportunities for using smaller and lower energies machines for the industrial processing of materials, the sterilization of components via accelerators still remain a small science laboratory activity. Furthermore the technical application of cost-effective pollution control, waste treatment etc. by accelerators have received little attention so far.

6. CONCLUSION

In the present day competitive global markets, technology transfer has a much wider brief than ever before. Large accelerator laboratories have the opportunity to participate in this arena by aligning <u>small</u> accelerator development alongside Big Machine programmes thereby creating a credible partnership with industry and contributing to the well-being of the population. Some culture change within the laboratories will be necessary to generate the motivation and develop the appropriate people for these activities. Organizations supplying the information and technology packages will be obliged to provide competence over a wider range of disciplines, to be conversant with legal and quality procedures, to possess project management skills and to demonstrate genuine commitment to service the customer's requirements.