Introduction

Research and Development in the Chemical and Pharmaceutical Industry, Third Edition. Peter Bamfield

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An Overview of the Scope and Contents of the Book

1.1
The Industry

Chemistry, due to innovations commercialised by the chemical and allied industries, has a long history of making major contributions to the welfare and development of mankind. Without the myriad of industrial applications of chemistry we would all be so much the poorer, especially in the developed world. Our health would be far worse than is nowadays imaginable and our lifespan much shorter due to untreatable diseases and poor methods of diagnosis. Food would be much less available and with less choice, whilst the clothing we wear would be less functional and aesthetically pleasing. Energy would be more costly and inferior, rendering all sorts of activities that today we take for granted, especially in our homes, non-viable. Rafts of new materials which have lead to new construction methods for household goods, buildings, and the means of transportation such as cars and aeroplanes, would not be available. Last but not least we would not have witnessed the immense changes in our means of communication, both audio and visual, that have occurred in the last 25 years.

However, if a group of people were asked for a definition of the chemical Industry there is no doubt that most would give answers that would not reflect its massive historical contribution to the well being of society. It is a paradox that chemistry and chemists are perceived by the public as good but that chemicals and hence the chemical industry as bad. This poor image is largely due to a legacy of poor environmental control by the industry that existed until the latter part of the 20th century, which has lead to continuing attacks even today from the environmental lobby. Ironically major improvements in the environment will come mostly from the innovation and drive, which is at the core of R&D within the Industry.

Against this background in the recent past, not surprisingly, many sectors of the industry sought to distance themselves from the main stream, not only for social and political reasons but also for a perceived economic advantage. For instance, those chemical companies which had a strong base in medicinal chemistry, demerged and aligned themselves with the biological sciences to become part of the international Pharmaceutical Industry. Similarly those based on developing technologies have wanted to be seen as entirely new industries e.g. the biotech industry. In this way these sectors hoped to be viewed, in the eyes of the general public and investors, as cleaner

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than the general Chemical Industry, making them more attractive to the world stock markets. However, even here there are hidden pitfalls, as has been demonstrated by the continuing debate over pesticides from the agrochemicals sector, the ongoing furore over GM crops, nanotechnology and "grey goo", whilst "big pharma" took a hit from its perceived behaviour in the third world as portayed in the the film The Constant Gardner, and accusations of overchanging for drugs in the US [1-6].

In spite of all these changes in this book, the term Chemical Industry will often be used in its broadest possible context, covering the pharmaceutical business, even if not specifically stated in parts of the text. The content will therefore be of relevance to all those professionals who are already working, or new recruits about to start, in the R&D function of any company which uses both chemical and biochemical processes to invent and produce products or services for commercial gain. This will

Table I1 Chemical and Allied Industries

Generic Groupings Type	*Example*
Raw and Bulk Materials	Petrochemicals Inorganic Minerals/ores Ceramics/Glass Detergents Surfactants
Fine Chemicals	Organic Intermediates Fine Inorganics
Specialities	Photographic Chemicals Dyes and Pigments Perfumes and Fragrances Adhesives Coatings Food Additives Electronic Chemicals Biocides Nanotechnology
Biological	Pharmaceuticals Agrochemicals Biotechnology Food Products
Polymers	Fibres Plastics Performance Materials
Services	Contract Manufacture Analytical Toxicology

encompass the raw material and bulk chemical producers, the manufacturers of fine chemicals and intermediates, the speciality and performance chemicals industries, the chemical biology science based industries such as pharmaceuticals, agrochemicals and food products, as well as those operating in the polymers and materials chemistry areas, and the providers of outsourced services e.g. contract research, contract manufacture, analysis, toxicology, efficacy testing and safety. These generic groupings are shown schematically, but not comprehensively, in Table I1.

There are several industries that employ many chemists, which are not normally classified as part of the Chemical Industry, e.g. Energy, Water, Food and Agriculture, and this book should be of value to the R&D Managers operating in these areas. Additionally the book will be relevant to those working within the research institutes, public health and trade association laboratories, where the working environment is essentially the same as within industrial R&D.

In the second edition of this book in 2003 two major activities, that had changed the structure of the industry since the first edition in 1996, were outlined; namely mergers and acquisitions and globalisation. These acitivities have continued without any lack of pace to the present day.

Globalisation, whilst nothing new for the chemical industry, has become an economic necessity in many sectors and is more often accompanied by some form of merger or acquisition. A classic case is that of the European colorant manufacturing industry [I-1]. At the beginning of the 1990s there were six major European companies involved in the dyes and pigment industries: BASF, Bayer, Ciba, Hoechst, ICI and Sandoz. Following a series of mergers and demergers, there are now only three companies: Ciba, Clariant and DyStar. The progress from the three to six is charted in Table I2.

The pharmaceutical industry has seen even more dramatic changes with mergers ands acquisitions on a mega scale. The origins of the some of the current, largest pharmaceutical companies are shown in Table I3 [I-6]

These changes, in what were formerly household names and symbols of the greater Chemical Industry, have been matched by dramatic changes in individual companies as exemplified by ICI in the UK. Some of the changes that occurred to this company during the 1990s are shown graphically in Figure I1 [I-2, I-3]. Similar changes have happened and are continuing in such former bastions as BASF and DuPont.

All these changes within the industry have implications for the R&D environment in which managers have to work. For instance, it is not uncommon for research

Table I2 Restructuring of European Dyes Industry

Year	*Merger Activity*
1993	ICI demerges its dyes business forming Zeneca
1995	Bayer and Hoechst merge dyes businesses to form DyStar
1995	Sandoz demerge dyes as part of Clariant
1996	BASF acquires dyes business from Zeneca
1997	Ciba forms Novartis, dyes go into demerged Ciba Specialty Chemicals
2000	BASF transfers dyes business into DyStar
2004	DyStar purchased by Platinum Equity

groups to be working on the same topic in China, India, Europe and the USA, enabled by rapid electronic communication systems that provide information on a 24 hourly basis. Management is most likely to be in a matrix, which operates across functional, cultural and time barriers and hence requiring a high level of coordination and different interpersonal skills from those used in a small, local R&D group. In other instances the Manager may be working in a company providing R&D to another company under an outsourcing contract, placing a different emphasis on certain of these interpersonal skills, such as negotiation. In this global environment the management of change is crucial.

1.2 The Role and Breadth of R&D

In this book the role of R&D in the Industry is specifically defined as follows:

> *The invention and development of products, processes, systems and services which will provide the company with a commercial opportunity.*

More broadly its role can be described as providing options, to colleagues in Marketing, for the potential growth of the business. In other words, R&D provides the opportunity whilst Marketing is charged with making the decision on whether to pursue this opportunity, and then with its commercial exploitation.

With pure or fundamental research the provision of commercial opportunities is, by its very nature, a long way into the future. However, in industry this is the final objective, no matter how far into the future, it is not science for the sake of science. This type of long-term work is uncommon in most chemical companies and at best only represents a very small fraction of total R&D budgets, even in the largest companies. It is often contracted out or carried out in collaboration with research institutes and universities, these bodies finding that it provides them with a useful source of funding and indeed a new role in the economic welfare of a country. The time frames and measures of success are quite different from product oriented research and when carried out in industry requires special management skills. This will be dealt with in Section C on innovation and creativity.

Table I3 Mergers of Pharmaceutical Companies

Original Companies	*Years*	*New Company*
Pharmacia, Upjohn , Monsanto, Warner Lambert, Pfizer,	1995, 1999, 2000, 2003	Pfizer Inc
Wellcome, SmithKline Beecham, Glaxo	1995, 2000	GlaxoSmithKline
Astra AB, Zeneca	1998–9	AstraZeneca
Hoechst, Roussel, Marion Merrel Dow, Rhone-Poulenc	1994, 1995, 1999	Aventis
Sandoz , Ciba Geigy	1996	Novartis
Squibb, Breistol-Myers	1989	Bristol-Myers Squibb

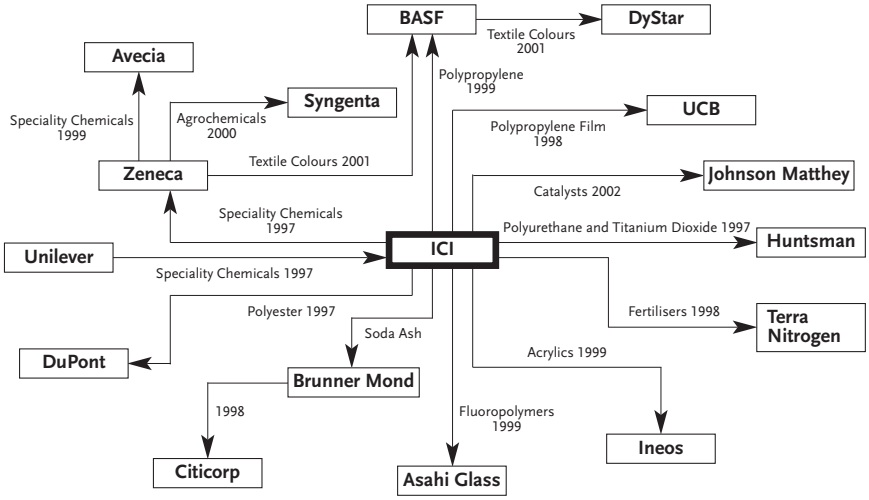

Figure I1. Change of Ownership of ICI Business 1993–2002

The heartland of innovation research, the R of R&D, in the Industry is the search for new products. These products will help to differentiate the company's product range from that of the competition, thus giving it a competitive edge in the market place. In order for this type of work to be done effectively by R&D it is very important to set clear targets. An R&D Manager must have an understanding of the particular market where the company operates, and especially recognise its driving forces. The R&D Manager also needs to work closely with colleagues in Marketing during the process of selecting and evaluating R&D targets. These important steps in the development pathway, or Innovation Chain as it is often called, will be described in Section D, which deals with Project Management.

In development, the D of R&D, there is a very strong overlap with the R&D people and those working in both manufacturing and marketing. They are all part of the operational function of the company and in these circumstances the R&D Manager will be required to be commercially astute. In addition to fitting into this matrix the R&D Manager has to be competent in working within very short time frames and in meeting deadlines. The ability to respond to circumstances, which may change rapidly, is also a necessary skill. The Project Management skills described in Section D are essential assets in helping the R&D Manager carry out this task in an effective manner.

Another area of R&D is that looking at new ways of applying or using existing chemical products; this is sometimes called applications research. It is often carried out alongside a technical service role to customers. It therefore has a very strong interface with customers in the world outside the company. In fact in many small companies, especially those operating in the speciality or performance chemicals area, this type of R&D is the only sort that is carried out. This is because its time frames are short and entry costs low, since it does not carry those associated with new product introduction, such as product registration. The R&D Manager in this environ-

ment is very much a part of the commercial arm of the company.

Good quality R&D work requires an excellent back up from what are called the support functions. These include analytical, information services and technology, intellectual property and regulatory affairs. The management of these functions, especially the laboratory based analytical service, requires many of the skills associated with core R&D and will therefore not be treated separately in any detail, except to point out their relationship and role within the organisation. Traditionally, the support functions were an integral part of a large company's R&D function but nowadays they are most likely to be outsourced under contract to external organisations specialising in a particular service, especially if these activities are not seen to offer a competitive advantage to the company. The organisation of outsourcing is not a simple matter and can often take up a significant amount of management time, especially if the contract is not negotiated in an effective manner. This will be covered in Section B.

1.3 R&D Organisation

The organisation of R&D is very dependent on the size, nature and the location of the Company which it serves. It is clear that, like almost everything else in life, there is no ideal organisational system that, if only we could set it up correctly, would produce the results required in a smooth and untroubled way. Organisations are always changing, mostly for the better, but not always if the changes are ill thought out and carried out in haste. There is a dynamic which switches from some form of functional management system to self managed teams or empowered organisations over a period of time, depending on the nature of the work, the company strategy or the prevailing socio-economic climate. However, the truly monolithic functional organisations, known as "first generation research", are things of the past as we have moved through the project lead R&D of the "second generation" into the market driven "third generation" organisations aligned directly with the company strategy [I-4]. We have now moved into the "fourth generation" where the management of knowledge has become a key role for R&D [I-5]. The issues involved in the different types of structures that exist within companies, especially chemical ones, will be covered in Section B.

Whilst a knowledge of these organisational structures is essential, a first time R&D Manager is most likely to be involved in the specific task of laboratory management. Laboratories come in all shapes and sizes and are used to perform a large variety of functions. These can range from superbly equipped synthetic and analytical laboratories in a major pharmaceutical company, semi-technical laboratories with larger scale reactors used to study the scale-up of reactions in a custom manufacturer's premises, technical service laboratories supporting a specific business with specialised equipment, to a sparsely equipped laboratory in a small company or a field trial station, remote from the centre of excellence. Whatever the situation in these laboratories they require the same basic set of the management

activities; employing the right people (Section A), providing the required equipment and support, controlling costs and budgets, ensuring good health and safety is practiced and that the work done is of the highest quality (Section B).

1.4 R&D Personnel

Since this book deals with the R&D functions in the chemical and pharmaceutical Industries, most, but not all, of the professional staff working in R&D will be chemists. The chemists will have been trained in the major disciplines, organic, inorganic, physical and biochemical, often having further specialised in areas such as polymers, colloid science, computational chemistry, analytical science, medicinal and bio-chemistry, photochemistry, process chemistry, etc as the move to a more interdisciplinary style of education has taken place. Other professionals will come from related scientific backgrounds, including biology, microbiology, medicine and genetics, botany and ecology, toxicology and environment, mathematics and physics. In the process development field there be a strong involvement in the management process by chemical engineers, as well as a close association with mechanical engineers, civil engineers and metallurgists.

The Industry is being increasingly organised around multi- or inter-disciplinary teams, with the edges between the various disciplines becoming blurred. Thus an R&D Manager in the modern, broadly based, multi-disciplinary, trans-national Industry is just as likely to be a chemical engineer, biochemist, biologist, microbiologist or physicist as a professionally trained chemist. Such a person will have to manage professionals from all of the other disciplines listed above, and probably others as well. In addition to the professionally qualified scientists, there will also be technical staff, often in the process of undergoing training, as well as some non-technical staff to be managed. With the arrival of the flatter organisation, career development for both the R&D Manager and staff has become more difficult, leading to a need for greater exposure activities outside the laboratory in the world of business, and further training as part of a process of continuous professional development. The human resource skills required to recruit and then manage the performance of the desired staff, together with related managerial activities will be considered in Section A.

1.5 Creativity and Innovation

Much has been written over the years on how to create the correct climate in which creativity and innovation will flourish. A great deal of this material is of an academic nature and tends to dwell on abstract themes rather than concrete ones. Section C, whilst not ignoring these "intangibles" is designed to offer practical advice on the steps which can be taken by an R&D Manager, in order to foster a creative climate and to assist the process of innovation. Included is a description

of the tools which can be used to help the creative process; the idea generation which is the starting point for any innovation. The protection, by patents and other means, of the intellectual property produced by R&D, together with the management of knowledge and possible ways in which it might be exploited is also covered in Section C.

1.6
Project Management

This is an extremely important subject and over the years many detailed, erudite and complex books have been produced dealing with its application in a variety of areas, but mostly outside chemistry R&D. It is beyond the scope of this book to go into great detail on project management. The emphasis in Section D of this book is on the selection and evaluation of the R&D targets, including portfolio management, together with a description of the practical application of the principles of project management to the innovation chain. The management of time along this innovation chain is a key issue, so that the new chemical products coming out of research can be delivered to the market in the shortest possible time. The nature of the project will define the managerial skill requirements of the project leader and these will be discussed in some detail.

Overview

By the end of this book the reader should understand the principles inherent in running a successful R&D organisation in any of the sectors of the Chemical, Pharmaceutical, Chemical Biology and allied industries. This will include knowing the requirements for harnessing the human resource, organising the environment for a climate of creativity and then managing the resultant innovations through to success in the market place.

References

[I-1] Bamfield, P., *The Restructuring of the Colorant Manufacturing Industry*. Review of Progress in Coloration, **2001**, 1–14

[I-2] Data taken from a presentation by Alan Smith, AZ-Tech

[I-3] Brophy, J., *Chemistry in Britain*, **2000**, **31**(4), 45

[I-4] Roussel, P.A., Saad, K. N., Erickson, T.J., *Third Generation R&D; Managing the Link to Corporate Strategy*, Harvard Business School Press, Boston, **1991**

[I-5] Miller, W.L, Morris, L., *Fourth Generation R&D, Managing Knowledge, Technology and Innovation,* Wiley, New York, **1999**

[I-6] Angel, Marcia, *The Truth about Drug Companies*, Random House, **2005**

[I-7] Royal Pharmaceutical Society, May **2004**, http://www.rpsgb.org.uk/pdfs/mergers.pdf