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The Experience of Obtaining ISO 9002 Certification for the Manufacture and Supply of Vitamins

Clive Conduit*

I want to talk to you today about the events and experiences which we encountered in obtaining ISO 9002 certification at the Scottish factory of *F. Hoffmann-La Roche*. I will give you an indication of the size and complexity of operations at the factory and I will also refer to those features which we discovered to be our strengths and weaknesses relative to ISO requirements. It was understanding these that enabled us to identify areas for attention and improvement. I will talk about the costs of certification, what I see as the benefits, the activities in which we are now engaged, and the things that we are planning for the future.

The reason we went for certification was because we believed we could not afford to be without it. We believed that customers would use ISO as a means of discriminating between potential suppliers and classifying them into different categories. We believed that customers would not ignore the fact that some suppliers had certification and others had not, and that there was every possibility that they would favour those who had obtained certification. There was also the possibility that customers would insist that they would only buy from suppliers who were certificated, and this we could not risk.

Firstly, let me put ISO 9002 into context.

This is the international standard for Quality Systems, being the model for Quality Assurance in Production and Supply or Installation. The Standard has other references depending on the controlling organisation. In the UK it is BS 5750 part 2 being administered by the British Standards Institution, whilst in the European Community it has the number EN 29002. The important fact is that in each version the details are the same, and the requirements are identical.

The location of the main *Roche* factories in the UK are as follows: At Welwyn North of London in England is the Pharma operation and the location of the Vitamins Manufacturing Unit is at Dalry in Scotland, 40 km Southwest of Glasgow. It is a large factory which occupies 30 hectares and currently employs 800 workers.

Now you should be aware that although I work in Scotland I am English and although the two countries have been united for nearly 400 years, there are between Scotland and England clear differences. The two countries have different cultures, different legal systems, different ways of speaking, and different education systems as well as having different eating habits and national foods. So, there is between the two countries what could be described as a sort of 'Röstigraben', and instead of there being a large canton to the North (as you would say) for Scotland there is a large canton to the South which is often referred to by the Scots people as the old enemy.

Some statistics of the factory are that it uses 120 t/h of steam, 10 000 m^3/d of water, and at any moment requires 25 megawatts of electricity to sustain all the operations.

The first challenge was to convince our Board of Directors, particulary our Managing Director at that time, that ISO 9002 would be worthwhile. This was not easy and for many months we were not able to persuade them that going for ISO would be a good thing. But there were two situations which eventually did make them reconsider the position. The first was that more and more customers were asking questions about ISO 9 000 and wanting their suppliers to become certificated. Secondly the progress being made by competitors towards certification was sufficient to suggest that we might be left behind and potentially lose business. So taken together these two aspects changed their minds, and we were given permission to embark on the preparation for ISO certification. It was then necessary to decide the extent of the scope of our certification. We had to decide whether we would select one production unit and obtain certification for that alone, after which we would progress to the other production units in turn, or whether we should go for the whole site and deal with all the production units at our first attempt. We decided to embark on the latter and it was finally decided that the scope of our certification should be:

The manufacture and supply of Vitamins B1, B5, and C.
The manufacture and supply of Vitamin Mixtures.
The manufacture and supply of organic chemicals.
The manufacture and supply of sodium sulphate and the manufacture and supply of hydrogen.

Organic chemicals and hydrogen are manufactured and used primarily for our own use at Dalry but any excess to our

**Correspondence*: C. Conduit
Quality Control Manager
Roche Products Limited
Dalry, Ayrshire KA24 5JJ
Scotland

Clive Conduit is a native of Nottingham, England. On leaving school he joined the laboratories of *Boots* the Chemists who have extensive factories in the area. He was trained as an analytical chemist and at the same time continued his studies at Nottingham Technical College and Loughborough University of Technology from where he graduated in Industrial Chemistry.
He then joined *Sterling* Organics, part of the *Sterling* Drug Group, at the factory which manufactured bulk pharmaceutical chemicals. He became analytical Manager in the Quality Control Department, being responsible for all analytical work.
In 1974 he joined *Roche Products Ltd.* at Dalry, the Scottish factory of *F. Hoffmann-La Roche AG*. In his role as Quality Control Manager he is responsible for Quality Control and Quality Assurance at the factory. He was responsible for all the preparations leading to the successful certification of the factory by the British Standards Institution to ISO 9002 and for the maintenance of the Quality System.
He is chairman of the Ayrshire Quality Association and a member of the Scottish Quality Network which undertake to promote Quality issues in a local and national context.

requirements is available for sale and for this reason they were included. Sodium Sulphate is a by-product of one of our processes which is sold on the open market and this explains the reason for its inclusion.

We then had to understand the philosophy of the Standard. This is not written down but it is my understanding of the way the Standard is meant to be operated. Firstly, it is necessary that you decide what you want to do. The second step is to write down how you want to do it. The obvious third step is to do it. Fourthly, you must record what you have done and fifthly, check that you have done what you said you were going to do. In other words conduct internal audits.

It is very clear that the system relies heavily on documentation and that external auditors assessing the effectiveness of the system would be putting most of their effort into the completeness, the correctness and the validity of this documentation system.

It was to our advantage at the factory that for many years we had had an extensive documentation system which had been expanded and refined as a result of our experience. This documentation included procedures and work instructions for production and related operations, specifications for in-process control and quality control together with associated test methods, batch records, analytical records, and quality control records.

We also had a number of other systems already in place such as internal auditing and complaints investigation which were required by the Standard.

However, we did recognise that there were some deficiencies which needed attention. Principally these were Procedures within our Purchasing and Materials Management operations, calibration, the completeness of our training records and certain aspects of document control.

Having identified these particular items we set about rectifying the situation by enlisting the help of those who worked in these areas and who had the necessary expertise, so that we might bring these particular items up to the requirement of the Standard. Whilst this was going on I began to compile our Quality Manual. This is not specifically required by the Standard but is generally recognised as being a very useful document. Certainly as far as the British Standards Institution is concerned, it is necessary to submit a Quality Manual prior to them conducting an assessment at the premises to ensure that the basic requirements of the Standard are being met.

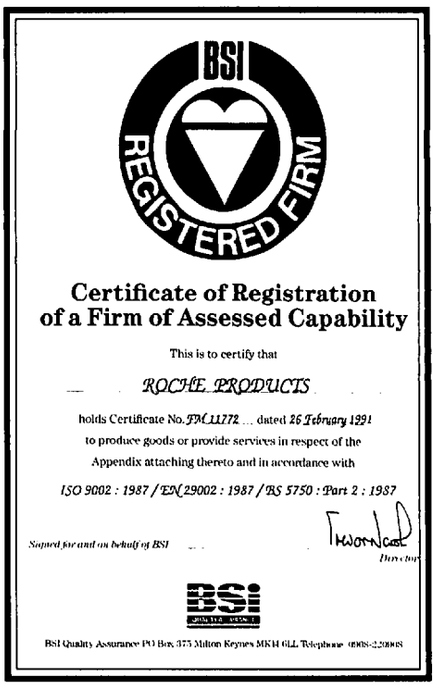
I decided on two principles as far as the Quality Manual was concerned. The first was that it should be a well produced, attractive and presentable document that reflected not only the work that had gone into its preparation but also that it represented the high quality system which was in operation at the factory. Secondly that it would be a readable distillation of our relevant procedures and operations. It was not to be a detailed account of everything we did because any small change in our operations would necessitate a change to be made to the contents of the Manual. So it was written as far as possible in general terms but without losing the essentials of the detail. It outlined the principles of our quality management system and working practices and referred to procedures rather than reproducing them.

It was also necessary to develop a Quality Policy and this is most certainly required by the Standard. Consultation with our Directors together with colleagues involved in quality and sales, we developed what we believe to be a relevant and concise and positive quality policy which is authorised by our UK Managing Director and our Divisional Director. This policy not only makes a commitment to our customers in terms of product quality and service quality, but it also includes a reference to the contribution and participation of each employee on the site. We recognise that employees can enhance or detract from the overall quality of our operations by the way in which they undertake their work and we take every opportunity to stress that they too have a vital part in the maintenance and improvement of our Quality System.

So eventually we considered that the work was sufficiently complete for us to be able to submit our Quality Manual to the British Standards Institution in order that they might come and conduct an assessment of our operations at the factory. They indicated that it would be many months before they would be able to do this and it was necessary for us to speak with them in order that this process might be speeded up.

In the meanwhile, however, I did contact a colleague from another company in the chemical industry who was prepared to come and give us a private assessment in advance of the auditors from the British Standards Institution. This was very valuable and enabled us to prepare ourselves for the sort of inquisition that we might have expected from the auditors themselves.

The assessment eventually took place at the beginning of December 1990. Two auditors from the British Standards Institution came to the factory for one week and assessed every aspect of our activity covered by our scope of certification. It


BSI
REGISTERED FIRM

Certificate of Registration of a Firm of Assessed Capability

This is to certify that

ROCHE PRODUCTS

holds Certificate No. FM 11772 dated 26 February 1991 to produce goods or provide services in respect of the Appendix attaching thereto and in accordance with

ISO 9002 : 1987 / EN 29002 : 1987 / BS 5750 : Part 2 : 1987

Signed for and on behalf of BSI ... Director

BSI QUALITY ASSURANCE

BSI Quality Assurance PO Box 375 Milton Keynes MK14 6LL Telephone 0908-220908

Fig. 1

was a very thorough audit although the length of time allowed did not permit them to go into every operation in great depth. This they only did for a random selection. I have to say it was a very impressive and well conducted audit and that the auditors were very positive, very pragmatic and very realistic in the assessment of our attitude and desire to comply with the spirit of the Standard. At the end of the week although they had noted a number of non-compliant items it was to our great relief that they indicated that they would be putting forward a recommendation that we should receive certification. The sort of things that they brought to our attention as minor items of non-compliance were that some of our materials management procedures were still not sufficiently detailed and that these would have to be amplified in order to more clearly explain the operations that were to be carried out. They also indicated that we would have to be much more detailed and extensive as far as our calibration of equipment was concerned, particularly with the calibration of critical measuring devices in the production units. They noted that in some areas document control was not as good as it should have been and it was necessary to tighten up in these particular areas.

Whilst they acknowledged that our internal auditing was well established and very thorough they did recommend that we should extend the auditing into other areas particularly the Engineering department and also the Purchasing and Despatch departments. They also pointed out that it was necessary that the internal auditing was itself audited. This we debated with the auditors, but their view was that

since members of Quality Control organised and performed the audits, the effectiveness of the auditing programme needed to be assessed by an independent person. Much to our embarrassment they did find that there was one occasion whereby some unauthorised amendments had taken place to an official record contrary to our own procedures and as a consequence they made a reference to this in their final report. We made an official response to all of the items which they had reported and in February of 1991 they sent us our Certificate to say that we were duly entered on the register of companies that were operating a quality system to the standards defined in BS 5750 part 2, ISO 9002 and EN 29002.

We arranged a formal presentation of the Certificate and asked the local representative of Her Majesty the Queen to come to the factory and to hand over the Certificate to our Divisional Director. *Fig. 1* shows the certificate which we received, which we are proud to display at our factory, and take pleasure in pointing it out to any visitors who come to see us.

There is a saying in English – 'If you have got it – flaunt it', so in addition we use this symbol (*Fig. 2*) on our correspondence in order to advertise the fact that we are a registered company certificated to ISO 9002 and its equivalents.

So having achieved Certification the challenge is now to ensure that the Standard is maintained. Some of the things that we undertake to ensure that we do not lose any the benefits of the hard work that we put into obtaining the Certificate in the first place are:

We have a Quality Review twice a year. This is conducted by our Divisional Director and involves the Production Manager, the Materials Manager, myself, and the Quality Assurance Officer. During these reviews we examine those aspects of site performance that are relevant to the Quality System. Things such as customer complaints, levels of rejection, the results of internal quality audits and other incidents that relate to quality. It is also necessary to formally review the Quality Manual to satisfy ourselves that it is still meeting the requirements that we intend.

Additionally we consider topics which could improve our Quality System and discuss ways of evaluating these.

We continue to audit our suppliers of materials as we did previously and to these we have added suppliers of services such as transport and distribution. This proves to be extremely useful, both for them and for ourselves, as it gives us an opportunity to say very clearly what we expect, and for them to highlight any uncertainties or difficulties that they may envisage.

Fig. 2

We have introduced quality topics into a number of our training modules in order that we might inform and encourage all levels of our workforce to participate fully in every aspect of maintaining the Quality System.

As part of these training programmes, we in Quality Control undertake to give talks on Quality to a wide variety of groups. We talk about the application of the Standard, particular aspects of quality on the site, quality initiatives, customer comments and quality incidents in order that they may be fully informed, and that we might get their participation and feedback in order to improve the overall Quality System. I believe that it is important that these talks on Quality are repeated at regular intervals. Quality is not static, it is dynamic. There are always details to communicate, matters to discuss, and principles to reinforce. The more we talk about Quality the better it will be appreciated, and the greater will be the willingness to participate in improvement projects. Of course, we continue to investigate customer complaints, and ensure that all who can assist in the investigation meet to discuss and attempt to resolve the situation. And we continue to conduct many internal quality audits in a variety of departments as a means of monitoring compliance with the requirements of our own procedures as well as the Standard.

So what have we learned as a result of going ahead with certification. We have learned that in addition to all the time and effort associated with the preparation and maintenance of the system it was not cheap. These are the actual costs. The original application fee was £7000 and it costs us a renewal fee of £700 each year. The assessor makes a return visit every six months and the total cost of this exercise each year is £1700. We learned that you need a champion. Someone who is committed to the concept of a Quality System and all that that means. Someone who is prepared to be persistent and to work away in encouraging and seeking the assistance of everyone at a factory to participate fully in what you are trying to achieve.

Now, had I been a Scotsman, I might have selected as an example of a champion someone from the long list of famous Scottish heroes. If I were Swiss I suppose I might have chosen *William Tell*. But since I am English, and from the City of Nottingham, I thought that *Robin Hood* would be an excellent example of a champion. Of course with all heroes from the past there is a lot of fiction mixed with fact. But you may like to consider these three features.

He was a person who walked with kings – but did not lose the common touch. He was able to relate to all levels of people – able to speak to and understand the needs of ordinary folk. In other words he was a good communicator. This is important. But the champion also needs to be a person of vision, clear sighted and looking ahead. Someone who can be a guide, who can warn of dangers, and give advice on the way forward. But on occasions, the champion needs to be a warrior – sometimes on the offensive in order to gain new ground, sometimes defending. Unfortunately, Quality philosophies are not universally accepted nor always regarded as a top priority. It is, therefore, necessary from time to time to be prepared to fight for what we believe is right. Sometimes we do not always win the battle, but that does not mean that we have lost the war.

We have also discovered that there have been a number of benefits which we perhaps had not envisaged when we first embarked on certification.

From the external point of view that is to say as far as our customers are concerned there have been a number of benefits. One reaction has been that of surprise that a factory like ours has not only decided to go for certification but has actually achieved it. Together with this is the satisfaction of knowing that the goods which they are receiving are from a factory that can demonstrate high standards of quality. Then there is the ready acceptance of the Company because there is a willingness to acknowledge that the goods which are being sold to them are manufactured, controlled and distributed according to a System with which they can identify. This in turn gives them confidence in *Roche Products* as being one of their approved suppliers.

From the internal point of view we have undoubtedly found that there has been a greater awareness of quality at the factory as a result of all the publicity and promotion that we have done.

There has been a greater involvement in quality issues by all levels of the workforce than previously and this has given rise to a much higher level of contribution particularly from operators and tradesmen

as those who are at the front end of manufacturing and maintaining the operations at the factory. And it has been a successful enterprise, because not only did we achieve certification, but also because we are maintaining and extending the quality initiative with the support of everyone. There is no doubt that getting ISO 9002 has given us an achievement in which we have all been able to share and of which we are all proud. It is this that has given us the encouragement to venture into other activities associated with improving the quality of our operations.

As far as the future is concerned we have plans to build on the foundation that has been created by obtaining ISO certification. We want to move on from here – from this foundation and develop a number of other quality initiatives that will lead us along the road to being a total quality managed site. The things that we want to do in the future involve consolidating everything that we have put into the quality system so that we continue to benefit from all that the system has to offer and the involvement of people.

We want to apply Statistical Process Control to all of our production processes and have already embarked on this in one of our production units. We intend to extend this in the months to come to the other units as well. For this purpose a large number of our chemists are undergoing training in the techniques associated with SPC.

We are also developing specific projects which might be classed under the heading of Continuous Improvement. These are associated with better performance, increased efficiency, better yield so that all across the site there might be a general raising of the quality of our operations.

We also want to develop systems whereby we can gather together all the costs of non-conformance not just in production areas but in all areas of the factory so that we might eliminate the waste of time, materials and money. Not only is this an important measure of the quality of operations at a factory, but it should also indicate that Quality is cost effective and can be used to make a positive contribution to profits. This at the end of the day is why we are in business isn't it?

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Vers la qualité totale: évolution ou revolution

Pierre Manhes*

Introduction générale

Au moment de l'élaboration de l'encyclopédie, et avant les profonds bouleversements de la fin du 18ème siècle, M. le *Marquis de Pompignan* dans le discours préliminaire à ses poésies sacrées, reprenait la querelle des anciens et des modernes et proférait en 1788:

'Quoiqu'en disent les plaisants du siècle, il vaut mieux ennuyer son prochain que le corrompre ou le pervertir'. Le reste de l'ouvrage, d'ailleurs, montre bien qu'en tout cas ce marquis-là ne pervertit personne.

J'ai bien peur de ne pas suivre l'exemple de ce sage et de réussir pour ma part l'exploit de corrompre mon prochain tout en l'ennuyant.

Mon propos sera d'essayer de clarifier ce que signifie la notion de qualité pour notre entreprise et comment elle y est mise en œuvre, à travers mes expériences, et donc ma perception de l'action de *Nestlé* dans ce domaine. Les discours d'anciens combattants sont souvent ennuyeux et l'objectivité n'est généralement pas leur fort. Merci donc de vos efforts à me suivre.

Introduction

Et d'abord, qu'est-ce que la qualité totale? Chaque époque amène son lot de sigles et d'expressions nouvelles qu'il est de bon ton d'utiliser pour paraître 'dans le vent'. Pourquoi n'en serait-il pas de même avec ce concept, et les esprits forts ne feraient-ils pas mieux d'attendre la naissance de l'expression suivante pour se gausser de ceux qui, à corps et à cris, se sont lancés à l'assaut de cet autre mirage organisationnel, nouvelle terre promise de managers romantiques et en tout cas source de profit des cabinets de conseils.

Je n'ai pas de définition originale mais quelques remarques s'appuyant plus particulièrement sur notre expérience:

- tout d'abord une définition est souvent une déclaration d'intention, et, comme dans une auberge espagnole, on trouve dans le concept de la qualité totale ce qu'on y apporte: qualité du produit, du service au client, définition du produit en fonction des besoins de la clientèle, amélioration de la productivité, flux tendu, et j'en passe. Les définitions varient d'une entreprise à l'autre, d'une circonstance à l'autre, et il faut distinguer le permanent et fondamental du circonstanciel.
- Ensuite, pour beaucoup d'entre nous, en partie à cause de ce qui précède, il ne nous est pas apparu au premier abord que le concept fut bien nouveau. Dignes émules de M. *Jourdain*, nous avions fait sans le savoir de la qualité totale depuis fort longtemps. En effet, plusieurs aspects de la culture de l'entreprise sont parties intégrantes, se redéfinissent, et se renforcent dans le concept de qualité totale.
- Par ailleurs, un nouveau concept n'élimine pas l'antérieur. Je ne considère pas que dans un édifice les fondations sont moins nécessaires que les étages supérieurs. Bien au contraire, je me propose dans ce qui suit d'expliquer le développement du concept de qualité dans notre entreprise étape par étape.

Pierre Manhes. Ingénieur Chimiste EFT Lyon, France. Carrière professionnelle chez *Nestlé*, d'abord dans le cadre de Quality Control au Venezuela, puis dans des laboratoires régionaux en Colombie et en Afrique du Sud, puis direction d'usine en Afrique du Sud et en Colombie. Il fut par la suite Directeur Technique au Danemark. Depuis fin 1990 il est Assistant du Coordonateur Technique de la Zone 1 (Europe).

**Correspondance*: P. Manhes
Nestec SA
Nestlé
CH–1800 Vevey