Very Personal Thoughts on the Past, Present and Future
No ...

- MHRA Inspections
- SOPs
- Validation
- Qualified Persons
- Site Master Files
- Dissolution
- Type 0, 1 etc.
- Computers
Good, hard working people ...
Dedicated, enthusiastic ...
Proud of "QUALITY" (?)

BUT WHAT ABOUT MANAGEMENT?

No News is Good News . . .
. . . as long as the goods were produced
FORTHCOMING LEGISLATION
ON THE SAFETY, QUALITY AND
DESCRIPTION OF DRUGS AND
MEDICINES

Presented to Parliament by the Secretary of State for Scotland,
the Minister of Agriculture, Fisheries and Food
and the Minister of Health
by Command of Her Majesty
September 1967

LONDON
HER MAJESTY'S STATIONERY OFFICE
Cmnd. 3395
1s. 9d. net
Guide to Good Pharmaceutical Manufacturing Practice

LONDON
HER MAJESTY'S STATIONERY OFFICE
Price 31½p net
Report of the Committee-appointed to inquire into the circumstances, including the production, which led to the use of contaminated infusion fluids in the Devonport Section of Plymouth General Hospital

Chairman
C. M. CLOTHIER, ESQ., Q.C., B.C.L., M.A. Oxon.

Presented to Parliament by the Secretary of State for Social Services by Command of Her Majesty
July 1972

LONDON
HER MAJESTY'S STATIONERY OFFICE
24p. net
Cmnd. 5035
1966-2007 thoughts ...

Legislation! ... Control!

SAFETY and QUALITY ...

... IMPROVED?

YES ... BUT
For most people the **two** most powerful experiences in life are **achieving** and **connecting**. This is because most of what grabs our attention and commands our energy falls into these two categories.

*Edward Hallowell, sociologist*
Achieving has to do with our accomplishments ... things like

- Pursuing career success
- Realising a difficult goal
- Winning contests
- Receiving words of deep affection
Connecting

Connecting has to do with our relational world ... things like

- Falling in love
- Forming great friendships
- Being cared for when we are sick
- Receiving words of deep affection
- Joining and participating in societies
- Talking with peers about mutual problems
Our society is increasingly devoted to, and obsessed with, and enslaved by achieving, and increasingly bankrupt and impoverished when it comes to connecting.
PQG Aims - Opportunities to Connect

- To provide a forum for open exchange of information and experience.
- To develop unified approach to pharmaceutical QA and GMP.
- To promote status of and represent QPs and other pharmaceutical QA professionals.
- To promote education and training in pharmaceutical quality.
- To manage a Supplier Certification scheme.
PQG Future

- Continue to survive.
- Permanent employees.
- Work with other societies
Industry Future. It has a “Problem”

£500M and 12 years to develop a new drug

Includes biologics. SOURCE: Datamonitor, PhRMA. Acumen Journal of Sciences, Vol 1, Issue II
Drug Development

Research
Years: 6-8

Development
1-2 1-2 1-2 1-2

12 Years, £500M

Registration

30-40% of all new drugs fail due to poor performance at the animal – human transition
Look, matey, I know a dead parrot when I see one, and I'm looking at one right now.

Owner: No no he's not dead, he's, he's restin'! Remarkable bird, the Norwegian Blue, idn'it, ay? Beautiful plumage!
Research Based Industry Challenge

- Astra Zeneca 38
- BMS 30
- GSK 23
- Novartis 14
- Pfizer 41
- Sanofi-Aventis 34
- Lilly 22
- Merck 22

The Blockbuster model is not sustainable
The FDA is chronically and critically underfunded. They regulate 25 cents of every dollar spent by Americans, and they have a budget of less than $2 billion. FDA’s budget is equivalent to that of a single school district. The whole situation is ludicrous. We are expecting 20 million lines of imports this year. We’ve seen a 16-fold increase in adverse drug events, we’ve seen doubling of direct to consumer television ads, a sixty-five percent increase in food imports, and FDA has had a flatlined budget.

Barbara Immel, Second Annual FDA Inspections Summit, October 23, 2007, Bethesda, USA
Agencies/Regulators Solution.

- Dump it on the QP and the Quality department.
Quality Management

QP should be involved in the implementation and maintenance of the Quality Management System.

QP should ensure that the product quality review is performed in a timely manner and is adequate!
Quality Control

- Results of on-going stability studies should be made available to key personnel and, in particular, to the Qualified Person!
EU guide to GMP, part 1, chapter 7

Contract Manufacture and Analysis

The QP needs to assure:

- The existence of a written contract
- Any proposed changes are in accordance with the MA
- A system to assess the competence of the contract acceptor
- All products delivered by the contract acceptor comply with the spec or are released by a QP
Active substances

QP’s responsibilities:

- Each API production batch satisfies the provisions of the Directive
- Compliance of the supplier with GMP
Immutable facts?

- If you are interested in a career get out of Quality, the job is becoming impossible.
Today and Tomorrow

- The QP and the Quality professional in the UK has an increasingly difficult and onerous task in meeting the Regulatory expectations.
- It is a personal and professional responsibility, which lays him/her open to Regulatory action.
- MHRA will take action against irresponsible, negligent and unprofessional QPs.
- Inspectors expect QPs to fulfill their legal duties in a professional manner.
1966-2007 thoughts ...

The LAW of DIMINISHING RETURNS

REACHED or EVEN EXCEEDED!
MHRA Help or Hindrance?  
1966 - 2007

- QP discretion!!!!!
- Pragmatism versus letter of law.
- I see no change at the agency.
- Industry is too subservient.
- I see no change in industry.

SO WHAT?
Go East and South
Research Based Industry Future

- A very few major players, how is your pipeline?
- Lots of niche players, what skills do you have?
- ?????
Consultants are an affliction sent by God, so that when there is no overt persecution in the company, the faithful may not be denied the merits of suffering.
Research and marketing are what matters. What happens in between can be done anywhere!

Alan Hearn, Managing Director, Syntex, 1987.
Manufacturing will move to the lowest cost option ... outsourcing

- Challenges
  - Different Countries
  - Different Languages
  - Different Time Zones
  - Different Cultures

- Must Haves
  - Excellent systems for communicating changes
  - Excellent systems for review
Personal Opportunities

- Biotechnology.
- Clinical Development.
- Pharmacovigilance.
- Managing Outsourcing.
- Counterfeit Prevention.
- Quality by Design.
- Regulatory Affairs.
- Consultancy.
- Sales and Marketing
- Be active in the PQG.
- Closing factories and moving products
- Emigrate.
Question.

Hi-8 MEL is a therapeutic vaccine for metastatic melanoma. It consists of two recombinant vectors, a plasmid DNA and a MVA virus. Both vectors encode the MeI3 polyepitope string derived from five different melanoma associated antigens.

Do You Understand?
Keeping Up-To-Date

... staying ahead of the game

- Regulatory
- Business
- Quality systems ... best industry practice

Hints for success ...

- Get ‘networked’. PQG. Don’t become INSULAR
- Adopt attitude of ‘Life Long Learning’!