**APPENDIX 1**

**Curriculum Vitae**

**Mrs Liz Allanson**

**BSc(Pharm), MRPharmS**

**Recognised Areas of Expertise:**

* EU GMP Pharmaceutical Legislation and Regulatory Expectations
* GMP and GDP Compliance
* Quality Management Systems
* Clinical Trial Manufacture/Packaging and QP Release
* Auditing and Mock Regulatory GMP Inspections
* Supply Chain Management

**Current Employment:**

**2004 to present day**

Independent Pharmaceutical Consultant

**Contracts primarily with:-**

**1. NSF-DBA Ltd -** contracted to deliver:

* Qualified Person Training
* Auditor Training
* External and In-house Training courses on all subjects associated with GMP, Quality Systems , Clinical Trial Supplies and Supply Chain Management
* Audits and Mock regulatory GMP inspections worldwide
* Consultancy, particularly in Inspection readiness

**2. Lowden International** – contracted to deliver

* Live Line Clearance ™ Implementation for packaging lines
* Quality Management System – design and implementation

**Involvement with Professional Associations/Societies:**

* Member of the Royal Pharmaceutical Society of Great Britain.
* Member of the Institute of Quality Assurance
* Member of British Association of Research and Quality Assurance

**Career History:**

* Qualified Person under the Transitional Provisions since 1985
* ISO 9001 Lead Auditor since 1993

**UK Medicines and Healthcare products Regulatory Agency (MHRA)**

**Sept 86 – June 2004**

**Positions held:**

**Feb 2002 – June 2004 Manager of GMP Inspection Unit.**

* Management of the inspectors and resources necessary to perform the GMP regulatory inspection programme of pharmaceutical manufacturers, distributors, importers, hospital manufacturing units and tissue banks.
* Management of the inspection expenditure budget and generation of an annual income of £ 2 million.

**April 2000 – Feb 2002 GMP Technical Manager**

* To provide technical leadership and guidance to all Inspectors in MHRA.
* To provide GMP technical input into development of EU legislation and to the MHRA
* To perform some of the more difficult, complex or politically sensitive inspections, often performed solo both in UK and overseas.

**Sept 1988 – April 2000 Regional Manager**

* Management and organisation of the N.W Regional office and of inspection activities undertaken by the Inspectors in the North West Region.
* Inspection of UK and overseas pharmaceutical companies, importers distributors and hospital manufacturing units against EC Directives and Good Pharmaceutical Manufacturing Practice and Good Distribution Practice.

## Sept 1986 – Sept 1988 GMP Inspector

* Performing approximately 100 Inspections per annum of pharmaceutical manufacturers (UK and overseas), distributors and hospital manufacturing units.

## NHS- St Helens and Knowlsey Health Authority - Sept 1974 – Sept 1986

**District QA Pharmacist - June 1979 – Sept 1986**

* Management of the District Pharmaceutical Quality Control Laboratory (including the Regional Microbiology service) and associated Quality Assurance activities.
* Final approval and release of medicinal products manufactured within the district pharmaceutical service.(Parenterals, Irrigations, sterile creams and ointments)

**Mr Peter Smith**

**C. Chem., MRSC, M. Inst. Pkg**

**Recognised Areas of Expertise**

* Medicinal Product Law and Inspections
* Quality Management Systems and GMP
* Packaging materials
* Statistics/SPC

**Current Employment**

* Associate with NSF-DBA (previously Partner until June 2004)

**Involvement with Professional Associations/Societies**

* Chartered Chemist and Member of the Royal Society of Chemistry
* Member of the Institute of Packaging
* Presenter at courses organised by the PQG, TOPRA, VAPI (Belgium), Macedonian Industrial Association, and at Interphex
* Articles in Panorama (Institute of Packaging)

**Career History**

* **1989 to date** – **Partner then (from 2004) Associate with David Begg Associates Ltd**. **York, UK:**
  + Preparing and presenting Training courses
  + Honorary Lecturer – University of Strathclyde
  + Auditing and Consultancy
  + Tutor at the Pharmaceutical Quality Group QA Courses
  + Specialising in Regulatory Controls of Medicines, Packaging, and Sterile Products
  + Tutor for the Pharmaceutical Quality Group – Code of Practice for Contact and Printed Packaging Materials (Sector scheme under BS5750 – now ISO9001)
* **1986 to 1989 – Principal Medicines Inspector, Department of Health, UK** (now known as the Medicines and Healthcare Regulatory Agency, MHRA)
  + Technical specialist for packaging and non-sterile products
  + Arranging Training courses for the Inspectorate group and mentoring new Inspectors
  + Presentations on behalf of the Medicines Inspectorate (at Interphex: Sterile Processing Standards and the Packaging of Pharmaceuticals)
  + Performing Regulatory Inspections in the UK and Worldwide – all dosage forms
* **1983 to 1986 – Area Medicines Inspector, Department of Health, Uk**
  + Performing Regulatory Inspections in the UK and Worldwide – all dosage forms
* **1981 to 1983 - Factory Manager, Unipack Ltd Billericay, UK**
  + Responsible for all aspects of Production and QA in relation to the contact Packaging of Pharmaceuticals (flexible packaging)
  + Acted as Qualified Person
  + Prepared and maintained Technical Agreements
  + Special experience in Clinical Trial Packaging systems and Cold Form Aluminium packaging (including paper on Cold Form Aluminium Packaging in Panorama – Institute of Packaging)
  + Prepared and presented company training programme/courses
* **1977 to 1981 – Sterile Department Manager then Site Manufacturing Manager, Kirkby Warrick Pharmaceuticals Ltd (a subsidiary of Schering Plough Inc.)**
  + Responsible for all aspects of manufacturing, packaging and storage of sterile products, non-sterile Liquids, Creams, Ointments, suppositories, tablets and cotton buds.
  + Acted as Qualified Person and named on CD Licence
  + Prepared company training programme/courses
* **1972 to 1977 – Production Planner, then Production Supervisor The Wellcome Foundation, Dartford, Kent (subsequently became part of the GSK group)**
  + Computer based production planning
  + Production supervision in Packaging, Sterile Products filling and Liquids Manufacturing Departments
* **1970 to 1971 – Quality Control Analyst – ICI Ltd Yalding, Kent (Industrial period of the ‘Sandwich Course’ leading to Grad. RIC)**
  + Analyst – developing GC methods and performing routine analyses