

## **Memorandum of Understanding**

### **Between**

The Health Protection Agency acting  
through its National Institute For Biological  
Standards and Control which expression  
shall include its successors in title,  
Blanche Lane, South Mimms, Potters Bar,  
Hertfordshire, EN6 3QG, UK;

**and**

Material Measurement Laboratory,  
National Institute of Standards and  
Technology, 100 Bureau Drive,  
Gaithersburg, MD 20899-1070, USA.

### **“The Parties”.**

1. This document constitutes a Memorandum of Understanding between the Health Protection Agency acting through its National Institute For Biological Standards and Control, UK, and the Material Measurement Laboratory of the National Institute for Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899-1070, USA. This Memorandum of Understanding is a statement of intent of the Parties to collaborate and is not a legally binding agreement. No legal rights or obligations are created by this agreement.

2. The Parties to this Memorandum of Understanding:

- Recognise the importance of high quality analytical science in ensuring the quality, safety and efficacy of biological and biopharmaceutical products, and ancillary materials, used clinically to treat humans;
- Recognise the importance of high quality analytical science in ensuring the accuracy and reliability of diagnostic procedures which aid the protection of human health;
- Recognise the key importance of well characterised reference materials both for ensuring the quality of biopharmaceutical products, diagnostic procedures and ancillary materials, and their manufacturing systems, and for monitoring and optimising the performance of analytical systems;
- Recognise that the application of these analytical methods is underpinned by an understanding of the underlying science, and of the sources and magnitude of the errors associated with these methods;
- Recognise the role of the role of various national and international organisations concerned in the calibration, and of the national and international organisation involved in the licensing and regulation of biological therapies and diagnostic procedures;
- Acknowledge the need for both Parties to be seen to be taking a neutral position with respect to Industry, and to manage carefully the potential for perceived and actual conflicts of interest;
- Share common goals of:
  - applying the best available science to the analysis of biopharmaceutical products and their production systems, to support regulatory authorities;

- applying the best available science to the development and validation of diagnostic procedures;
- the development of reference materials which support the development and application of diagnostic procedures, and analytical approaches to ensuring the quality of biological therapies;
- Enhancing international harmonisation of the use and calibration of these methods;
- Believe that coordination of complementary activities could help facilitate these goals.

3. The Objectives of the Parties are to:

- Promote scientific collaboration in development of methodology for understanding the structure, purity and biological activities of current and potential biological medicines, the accuracy and reliability of diagnostic procedures, and ancillary materials related to these two aims;
- To promote the development and acceptance of reference materials which support the development, application and regulation of biological therapies and of diagnostic procedures;
- Work together to promote the harmonisation and validation of methodology to achieve the objective above.

4. The Parties agree to create a steering committee composed of a principal and associate from each party to:

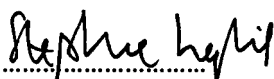
- identify shared priorities;
- create the model(s), both technical and financial, that foster collaboration and cooperation;
- consider the following areas for potential collaboration:
  - establishing a molecular basis for biological activity;
  - standards for cellular measurements;
  - standards for genetic testing;
  - standards for clinical proteomics;
  - measurement methods and standards to support "Follow-On Biologics/Biosimilars";
  - Collaborative research agreements leading to joint publications and validated methods;
  - Education or training programs and meetings for topics of mutual interest.

5. Prior to commencement of any activities under this Memorandum of Understanding, the Parties shall enter into a legal agreement to detail the respective responsibilities, both financial and practical, of each party. Where commercially valuable intellectual property rights or materials are likely to arise from collaborative work, the Parties will negotiate in good faith to allocate appropriate returns. Activities contemplated under this Memorandum of Understanding are subject to the availability of funds and other necessary resources. This Memorandum of Understanding does not obligate funds.

6. This Memorandum of Understanding is for a period of 5 years in the first instance, and will be reviewed at the end of this period. Each party has the right to Terminate the Memorandum of Understanding upon 60 days written notice to the other party. Termination of the Memorandum of Understanding will not terminate activities entered into by the Parties under separate legal agreements.

7. Both parties retain the right to enter into agreements with third parties to carry out similar activities.

FOR THE HEALTH PROTECTION AGENCY

Dr. Stephen Inglis 

Director, NIBSC

Date: 17<sup>th</sup> February 2011

FOR NIST MATERIAL MEASUREMENT  
LABORATORY

Dr. Willie E. May 

Director, MML

Date: 17 February 2011