

## Dr Catrina (Cat) Stirling

### Vaccine batch to vaccine batch comparison by consistency testing (VAC2VAC)

Authors: Catrina Stirling<sup>1</sup>, Denis Lambrigts<sup>2</sup>, Sylvie Uhlich<sup>3</sup>, Coenraad Hendriksen<sup>4</sup>, Odile Leroy<sup>5</sup>, Paul Sticking<sup>6</sup>, Elisabeth Balks<sup>7</sup>, Anke Huckriede<sup>8</sup>, Arjen Sloots<sup>4</sup>, Marlies Halder<sup>9</sup>, Joris Vandeputte<sup>10</sup>, Hilde Depraetere<sup>5</sup>

VAC2VAC brings together a unique One Health consortium of human and animal health pharmaceutical companies, academia, translational research organisations, Official Medicines Control Laboratories and regulatory bodies with the overall objective to demonstrate proof of concept of the consistency approach for batch release testing of established vaccines. This means that animal-free assays - instead of animal tests - can be used to ensure that each vaccine batch produced is consistent with a batch already proven to be safe and efficacious in registration studies or in clinical use. Hence the name "consistency approach". It covers vaccine potency, safety and animal welfare. The project aims to promote global understanding and acceptance of these new non-animal methods to facilitate international harmonisation and improved vaccine availability globally.

The three main steps to reach these objectives are:

#### 1) Development of new or optimisation of existing non-animal methods for consistency testing

This is the core activity of the project, with a focus on development and optimisation of physico-chemical methods, immunochemical methods, cell-based assays, and multi-parametric assays & bioinformatics.

#### 2) Pre-validation of selected methods

For selected methods developed in VAC2VAC, small-scale multi-centre studies will be set up to assess the transferability and inter-laboratory reproducibility of the methods. Methods that are successful in these pre-validation studies and that are proposed for inclusion in regulatory monographs, will be submitted to the EDQM Biological Standardisation Programme to be considered for further validation studies.

#### 3) Regulatory acceptance of the consistency approach

To maximise the chances of regulatory acceptance and implementation of the consistency approach for batch release, the development of methods in VAC2VAC will involve close cooperation between public partners and industry partners in consultation with the regulatory bodies. The presentation will outline the project in detail and discuss some early results and end with a summary of the approach, progress and next steps for Rabies vaccines.

(1) Zoetis Belgium SA, (2) GSK Biologicals, (3) Sanofi Pasteur, (4) Institute for Translational Vaccinology, (5) European Vaccine Initiative, (6) National Institute for Biological Standards and Control, (7) Paul-Ehrlich Institut, (8) University Medical Center Groningen, (9) European Commission, Joint Research Centre, (10) International Alliance for Biological Standardization for Europe

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