DAY 1 – 25th SEPTEMBER 2018 (Tuesday)
Chairs: Christina von Hunolstein / Mike Ward

8:30 – 8:50 Registrations

Session 1 – Opening and welcome speeches

9:00 – 9.15 Welcome speech
Professor W. Riccardi, President Istituto Superiore di Sanità (ISS)

9:15 – 9.30 Opening address
Mr Michael Ward, Coordinator Regulatory Systems Strengthening (RSS), WHO Headquarters, Geneva

9:30 – 9.45 Welcome address
Dr Carlo Pini, Director National Centre for the Control and Evaluation of Medicines (CNCF), ISS

9:45 – 10.00 Special address
Dr Giulio Pisani, Director Biologicals and Biotechnologicals Unit, ISS

10.00 Group photo

10:15 – 10:45 Coffee / tea break
10:45 – 11:15 **Session 2 – Meeting information and update since 2017**
- Brief introduction (Dr Ute Rosskopf)
- Adoption of the agenda (Mr Mike Ward)
- Terms of Reference of the 2nd General Meeting (Mr Mike Ward)
- Housekeeping information (Dr Ch. v. Hunolstein)
- Update on activities / achievements since 2017 meeting (Dr Ute Rosskopf)

11:15 – 12:30 **Session 3 – Presentations by network members**
- Brief updates by national control laboratories (NCLs)

12:30 – 13:45 **Lunch break**

13:45 – 15:15 **continuation Session 3 – Presentations by network members**
- Presentations by newly participating national regulatory authorities (NRAs) / NCLs

15:15 – 15:45 **Session 4 – WHO regional NCL networks**
- WHO Western Pacific Region (WPR): WPR National Control Laboratory update and risk based lot release (Dr Jinho Shin)
- WHO South-East Asia Region (SEAR): South-East Asia Regulatory Network (SEARN) (t.b.c.)
- WHO Eastern Mediterranean Region (EMR) (Dr Houda Langar)

15:45 – 16:00 **Coffee/tea break**

16:00 – 16:15 **Session 5 – Information from manufacturer associations**
- Proposal for discussion submitted by the Developing Countries Vaccine Manufacturers Network (DCVMN) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (DCVMN / IFPMA /Dr Ute Rosskopf)

- Closing remarks for Day 1

16:15 – 16:45 **Session 5 – Closed session for Network full members**

16:50 – 17:45 **Visit of ISS Museum** (1st visit: 25 persons)

*** SOCIAL DINNER ***
DAY 2 - 26th SEPTEMBER 2018 (Wednesday)
Chairs: Carlo Pini / Ute Rosskopf

9:00 – 10:30  Session 1 – Network SharePoint
- SharePoint update information (Ms Alaa Magdy)
- SharePoint validation (Dr Alexandrine Maes)
- SharePoint demonstration (Ms Alaa Magdy & Dr Alexandrine Maes )

10:30 – 11:00  Coffee/tea break

11:00– 12:30  Session 2 – Network SharePoint: Information-sharing
- Annual vaccine quality report (Dr Martijn Bruysters)
- Discussion of DCVMN & IFPMA proposal

12:30 – 13:45  Lunch break

13:45 – 15:00  Session 3 – Reliance and mutual recognition
- Reliance on shared information (plenary session)
- Work in groups
- Outcome of working group discussions (plenary session)

15:00 – 15:30  Coffee/tea break

15:30 – 16:30  Session 4 – Project update
- Update current projects (Dr Ute Rosskopf)
- Vaccine profiling (Dr Michael Gilgen)

- Wrap-up
- Closing remarks for Day 2

16:30: 17:00  Closed session for Network full members

17:15 – 18:15  Visit of ISS Museum (2nd visit: 25 persons)

DAY 3 – 27th SEPTEMBER 2018 (Thursday)
Chairs: Christina von Hunolstein / Ute Rosskopf

9:00 – 10:45  Session 1 – Sharing best practices: Quality control methods – new developments
- Introductory speech: 3Rs achievements and perspectives (Prof Coenraad Hendriksen)
- "Suitability of alternative adenosine triphosphate potency assay for lot release of Tokyo Bacillus Calmette-Guérin vaccine in Thailand" (Mrs Wereyarmarst Jaroenkunathum)
- “Pyrogen testing of human vaccine by Monocyte activation test” (Dr Marilena P. Etna)

10:45 – 11:15  Coffee/tea break

11:15 – 13:00  Session 2 – Sharing best practices: Harmonization
- “VAC2VAC = Vaccine batch to vaccine batch – Comparison by consistency testing” (Dr Ch. v. Hunolstein)
- “Inclusion of WHO protocol (Hib vaccine testing by HPAEC) into the Indian Pharmacopeia” (Dr Ch. v. Hunolstein)

13:00 – 14:30  Lunch break

14:30 – 16:00  Session 2 – continuation Sharing best practices: Harmonization
- WHO Rabies vaccine potency determination by serology (Dr Ralf Wagner)
- DCVMN workshop Hyderabad 2018 - Topics for discussion:
  - International collaborative study replacement Rabies NIH test
  - Replacement of Kendrick test for whole cell Pertussis vaccine
  - Acceptance of paralysis endpoint (T3 stage) for Tetanus challenge tests by NRAs (Dr Gopal Singh, DCVMN)
- Use of human endpoints for animal based challenge tests (Dr Ute Rosskopf)

16:00 – 16:30  Final discussions and Closing Session