



Meeting of the Network of National Vaccine Quality Control Laboratories (RRLNCCV)

Workshop for the Implementation of SPC Explorer RT Software
for the Management of Control Charts in Vaccines Quality Control Laboratories

(Taller para la Implementación del Programa SPC Explorer RT
en el Manejo de Gráficas de Control de la RRLNCCV)

Rio de Janeiro, Brazil
16 – 19 of June, 2008

The general objective of the workshop was to implement the software SPC Explorer RT and to summarize the performance analysis of potency tests of standards. The specific objectives were as follows:

- To give the countries basic statistical knowledge for the analysis of vaccine quality control charts
- To familiarize the countries with statistical process control software, SPC Explorer RT
- To translate the results of potency values of standards used in the quality control of vaccines of the countries into SPC graphs.
- To distribute SPC Explorer RT licenses for statistical analysis of vaccine quality control charts to the participants of the vaccine quality control laboratories

The meeting was developed according to the proposed agenda (Annex 1). It spanned over 4 days and was divided into 3 parts.

In the first part, an expert on statistical process control (SPC) analysis and management gave basic statistical training to the countries over course of two days. In addition, a member of the French Agency of Health Products Safety (AFSSAPS) contributed his knowledge and experience in the use of statistical process control software. In the second part, the laboratory representatives of the countries implemented the software and performed various practice case studies by using SPC Explorer RT software. In the last part, each country used SPC Explorer RT to translate their potency values of standards into analyzable graphics. More specifically, the graphics obtained were Individual/ X-Bar Charts accompanied by Moving Range Charts.

In conclusion, the countries' participants gained basic statistical knowledge for the purpose of vaccine quality control charts. More specifically, they were taught the analysis of vaccine quality control charts by using the statistical process control software, SPC Explorer RT. Moreover, the countries were then able to make potency testing graphs on location. Finally, each of the countries' representatives took one license of the software to their laboratory, giving them the opportunity to familiarize themselves with the broad applications of the software.

ANNEX 1:

TENTATIVE AGENDA

DAY 1	
9:00 – 9:30 AM	Opening: PAHO Representative, INCQS Representative
9:30 – 10:00 AM	Objectives and Logistics of Meeting <i>Dr. María de los Angeles Cortés, Regional Advisor of Vaccines and Biologicals, PAHO</i>
10:00 – 11:00 AM	Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>
11:00 AM	Coffee Break
11:15 – 1:00 AM	Cont ... Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>
1:00 PM	Lunch Break
2:00 – 5:00 PM	Cont ... Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>

ANNEX 1 (Cont):

DAY 2	
9:00 – 11:00 AM	Cont ... Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>
11:00 AM	Coffee Break
11:15 – 1:00 AM	Cont ... Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>
1:00 PM	Lunch Break
2:00 – 5:00 PM	Cont ... Basic Statistical Elements <i>Matthew Savage, PQ Systems</i>
DAY 3	
9:00 – 11:00 AM	AFSSAP Experience with SPC IV Software <i>Dr. Bertrand Poirier, AFSSAPS</i>
11:00 AM	Coffee Break
11:15 – 1:00 AM	Cont ... AFSSAP Experience with SPC IV Software <i>Dr. Bertrand Poirier, AFSSAPS</i>
1:00 PM	Lunch Break
2:00 – 5:00 PM	Cont ... AFSSAP Experience with SPC IV Software <i>Dr. Bertrand Poirier, AFSSAPS</i>
DAY 4	
9:00 – 11:00 AM	Use of SPC Explorer for the Countries. Capture of the Countries' Results <i>Argentina and Brasil</i>
11:00 AM	Coffee Break
11:15 – 1:00 AM	Use of SPC Explorer for the Countries. Capture of the Countries' Results <i>México, Venezuela and Colombia</i>