First DCVMN initiative breaking new ground for vaccine manufacturing facilities compliant with global GMP

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On 28th October 2014 DCVMN launched four new initiatives to support members engagements in large scale global supply of vaccines (cf. http://www.dcvmn.org/news/dcvmn-international-develops-multiple-initiatives-accelerate-access-affordable-high-quality. The new initiatives include sponsored mock-audits, offering a unique opportunity for manufacturers to collaborate informally with international engineering experts for the review of concept design of facilities and equipment to comply with global WHO GMP standards and guidelines (TRS).

Corporate members voluntarily applied for the mock-audit studies by submitting a letter of expression of interest and a dossier. Five companies signed a Memorandum of Understanding, and sponsored mock-audits were completed between January and April 2015.

The opportunity to serve a pool of manufacturers attracted the interest of high-profile audit experts with international experience, who otherwise would not consider such task on a one by one basis, due to the small size of individual projects, and uncertainty for follow up.

Manufacturers could choose the experts of independent engineering companies, with the condition of not being the same engineering company that designed or built the plant to be reviewed, as best practice in avoiding conflict of interest. The 2-3 days site visit reviewed bulk production, formulation and filling, QC and packaging areas, warehouse, and animal house, if available. The mock-audit results remain confidential and were communicated only to the manufacturer, and serve as basis for internal discussions or with potential partners to accelerate plans for expanding global access to vaccines.

The following excerpts of an anonymous survey were provided by participating manufacturers:

> *"The mock-audit not only identified many existing gaps between our facilities and WHO PQ standards, but also deepened our understanding for WHO GMP. This can be very helpful for us to bridge the gaps identified and accelerate our products into the PQ process."*

> *"The mock audit has been very helpful to identify or confirm deficiencies with level of compliance, to listen to recommendations, to elaborate feasible and affordable solutions (in terms of revamping facilities & equipment , training, review of SOPs), to prepare preliminary budget and to focus our efforts on the WHO prequalification with a maximum of efficiency …"*

"We highly appreciated the professional comments and advice provided by the service provider for this mock audit. Through this activity, the design of the facility, including production process, material and personnel flow, filling process, HVAC and water system has been fully discussed on GMP compliance. Additionally, the team has better understanding about quality in accordance with WHO PQ requirements. … issues of the facility design have been pointed out and the suitable solutions also have been fully identified. In sum, this mock audit supported by DCVMN really helps the improvement in product quality for the future, and we will keep working on it."

The project raised confidence in vaccine manufacturing facilities, leading to new ways to advance in operations towards improving global supply of needed vaccines at large scale.

A second call for expression of interest will be launched soon, making this opportunity available to more vaccine manufacturers willing to engage in global access to vaccines. Please let us know of your potential interest.

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Developing Countries Vaccine Manufacturers Network

DCVMN International

On behalf of the DCVMN Grant Advisory Committee