

DCVMN Annual Report 2015

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EXECUTIVE COMMITTEE MEMBERS



Mr. Mahendra Suhardono
President
Bio Farma, Indonesia



Mr. Rajinder Kumar Suri
Vice President
Panacea Biotech Limited, India



Dr. Akira Homma
Treasurer
Bio-Manguinhos (Fiocruz), Brazil



Mr. Rayasam Prasad
Biological E. Limited, India



Ms. Meng Li
China National Biotech Group Co.Ltd., China



Mr. Patrick Tippoo
The Biovac Institute, South Africa



Mr. Juliman
GAVI Board Alternate
Bio Farma, Indonesia



Dr. Steven Gao
Xiamen Inovax Biotech Co. Ltd., China



Mr. Adar Poonawalla
GAVI Board Representative
Serum Institute of India Ltd., India



Dr. Sonia R Pagliusi
Executive Secretary
DCVMN International

Message from the President

Dear Members, Partners and Friends,

DCVMN and its members continued to prosper in the year of 2015. We heartily welcomed four new members into our Network: Arabio, a biopharmaceutical company specialized in human vaccines and plasma products from Saudi Arabia; VINS Bioproducts, from India, who started off as an anti-snake venom serum producer, and now manufactures anti-rabies serum, as well as anti-rabies vaccine; Bravovax from China is in the process of developing rotavirus and other vaccines; and Institute of Medical Biology of the Chinese Academy of Medical Sciences (IMBCAMS) also from China, a specialist in Polio and other vaccines.

In 2015, DCVMN members continued to play an essential role in global vaccine supply, providing high-quality vaccines for all people. We praised the launch of the world's first Sabin-IPV vaccine made by IMBCAMS in China: the development of Sabin-IPV had long-time been sought by the Global Polio Eradication Initiative, taking us one step closer to a polio-free world. Towards the end of the year, Eubiologics, from South Korea, received WHO Prequalification for their oral cholera vaccine. Their success sets the stage for great collaborative models among members, as Green Cross Corporation supported Eubiologics in this endeavor, demonstrating the power of partnerships. We hope that all DCVMN members can write further success stories and proactively collaborate with our corporate members and international organizations.

DCVMN and its members have committed to improve access to vaccines through a Memorandum of understanding, working together to sustain global supply of needed-vaccines to prevent and remediate global vaccine shortages. At the same time maintaining production of high-quality vaccines to control epidemics and emergency outbreaks is a priority.

Through strong partnerships and harmonious collaborations, DCVMN members are rising to the challenge to supply quality vaccines to all people, and are building trust in the industry of emerging countries.

I look forward to celebrating the success of each member in the coming year, with a collective effort to work towards the ultimate goal of protecting healthy lives.

Sincerely,



Mahendra Suhardono
DCVMN President

DCVMN Members committed to boost global access to high-quality vaccines

DCVMN Corporate Members



DCVMN Member companies have reached an understanding to cooperate in an effort to increase and maintain the number of WHO prequalified vaccines available for international procurement, and to achieve a more sustainable and secure supply of priority vaccines, as identified by global health agencies such as WHO, UNICEF, PAHO and Gavi, the Vaccine Alliance. All corporate members are invited to join the effort.

The agreements highlight the principles of Global Access to ensure the development, manufacture and delivery of vaccines available and accessible in terms of quality, quantity and affordability to people in need in the developing world. For that purpose DCVMN members are committed to Global Access to vaccines through a Memorandum of Understanding - between DCVMN and Member Companies - that provides a mechanism through which they can work together at both a strategic level and a specific project level.

DCVMN Member Companies share the common goal of protecting people from infectious diseases, by accelerating access to affordable high-quality vaccines: "Our focus is twofold: high-quality vaccines for all people and dialogue with stakeholders, to assist manufacturers in getting the knowledge, tools and skills required to attain and maintain WHO prequalification status giving access to priority vaccines", emphasized Mahendra Suhardono, President of the Network.

Gavi CEO as special guest with DCVMN Executive Committee



Geneva, 13 April 2015

The Executive Committee of DCVMN had the pleasure and honour to host a dialogue with a special guest, Dr. Seth Berkley, Chief executive Officer of Gavi, the Vaccine Alliance.

The informal dialogue was around the sustainability of vaccine supply to close the immunization gap between wealthy and the world's poorest populations. Many of the 44 DCVMN corporate members, based in 16 developing countries and territories, have supported Gavi over a decade by supplying high-quality prequalified vaccines, when and where needed. Berkley conveyed the news that the commitments made by donors at the recent Gavi Pledging Conference will enable to immunize additional 300 million children in poor countries between 2016 and 2020, and recognized the importance of the DCVMN constituency in supporting the al health achievements, in making the world a healthier place, through most affordable vaccines available to Gavi.

DCVMN members' progress in global vaccine supply

The Oral Cholera Vaccine successful PQ by Eubiologics through collaborations

On 23rd December 2015, the oral cholera vaccine (OCV) produced by Eubiologics was approved by WHO as one of the pre-qualified vaccines for United Nations procurement. The OCV was manufactured through technology transfer in collaboration with the IVI, and Green Cross Corporation and GHIF have also supported the success of this project. According to GAVI, endemic cholera exists in 43 GAVI-eligible countries, causing a total of 1 million deaths globally each year. With the WHO-pre-qualified OCV, Eubiologics is aiming to reach a stockpile of 20 million doses per annum, to be financed through GAVI. The stockpile is expected to aid global responses to outbreaks, as well as improving overall availability and supply of OCV, especially in GAVI-eligible endemic countries.



This success is an excellent example of the effectiveness of international collaborations as well as partnerships between DCVMN members' and we hope in the future more members will be inspired to be agile in global supply.

More information:

http://www.who.int/immunization_standards/vaccine_quality/pq_298_euvichol_1dose_eubiologics/en/http://www.eubiologics.com/ENG/eng_product/euvichol_02.php

The world's first Sabin-IPV manufactured by IMBCAMS approved by CFDA

On 30th June 2015, the world's first Sabin-IPV produced by IMBCAMS was launched into the Chinese market, after obtaining approval from CFDA. The development of Sabin-IPV started in 1983, when an initiative was launched by the WHO as part of the endgame strategy for global Polio eradication.

As one of the priorities of the Global Polio Eradication Initiative, WHO launched a first call in 2012 for expression of interest to vaccine manufacturers to produce Sabin-IPV in 2012. Sabin-IPV is considered safer than traditional IPV production, in the event of unintentional or intentional release of poliovirus strains by the manufacturer.

A dossier for WHO pre-qualification is being prepared. Once IMBCAMS's Sabin-IPV is approved, the production capacity is presently between 7 and 15 million doses annually may be increased, which will bring us one step closer to sustainable global Polio eradication.



More information:

http://www.imbcams.ac.cn/Category_2142/Index.aspx

Grant to Shanghai Zerun Biotechnology to improve women's access to low-cost HPV vaccine

In September 2015, Zerun Biotechnology in Shanghai, a subsidiary of Walvax Biotechnology Ltd., China, received a grant with the aim of improving women's access to low-cost bivalent Human Papillomavirus (HPV) vaccine.



HPV infection is associated with cervical cancer. It is recommended by the WHO and other health authorities for young women to be vaccinated against HPV. The development of HPV vaccine is designed for supply to women in GAVI-supported countries and thereby reducing the risk of women developing cervical cancer due to human papillomavirus infection.

Cf. <http://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1127764>

DCVMN International office relocated to new premises



In 2015, DCVMN Secretariat office relocated to new premises in Nyon, Switzerland. In proximity with numerous international organizations including GAVI, ICRC, MSF, WHO and other UN offices, it is more likely to foster dialogue, aiming to facilitate communication with multiple international stakeholders, and promote global visibility of our Network.

Connecting the world for a cause



A series of six webinars was held throughout the year 2015. Respected experts were invited to share their precious knowledge with our members, taking advantage of the power of online communication technology, in connecting with our members all across the globe.

Date	DCVMN Quality Management webinars title	Speakers	No. of participants from DCVMN	Host
31 March 2015	Good Governance and Ethical Codes What They Are and Why They Matter for Vaccines	Mr. D. Curry	n.a	DCVMN
11 June 2015	Manufacturing flexibility: viral vaccine production	Dr. M. Lundgren	6	DCVMN
10 Sept. 2015	Reducing the TCO of vaccines manufacturing through a ready to fill primary packaging solution	Mr. A. Zambon	5	DCVMN
11 Nov. 2015	Registration of vaccines: current challenges and opportunities (English)	Dr. N. Dellepiane	15	DCVMN
12 Nov. 2015	Registration of vaccines: current challenges and opportunities (Spanish)	Dr. N. Dellepiane	27	DCVMN
09 Dec. 2015	WHO Platform Technologies	Dr. D. Wood	10	DCVMN

The RIGHT to KNOWLEDGE

A series of workshops have been organized by DCVMN and partners, focusing on several topics of Quality Management Systems. The aim of the workshops is to provide all members the relevant knowledge from international experts, to foster continuing improvements and innovation in vaccine manufacturing. Participants were encouraged to disseminate the knowledge in-house to benefit their fellows, benefiting a larger number of professionals by training a few people at a time. In practice, members were highly interested in participating at workshops, with an average of 58 participants per workshop. So far of 7 training workshops were organized (1 in 2014 and 6 in 2015), serving a total of 412 participants, exceeding proposed commitments.

Follow-up in-house training allowed creating a "multiplier effect" to further increase the number of professionals to receive the knowledge shared on specific topics to over a 1000 professionals from member companies. Two professionals of Cadila Biopharma rapidly engaged in the training programme, by implementation of in-house training to another 40 participants, as reported below.



Daily Mirror

Only for Internal Circulation | www.cadilapharma.com



July 23, 2015 | Thursday

Training on Quality Management System at Dholka facility

A training program on 'Quality Management System (QMS)' was organized by HR at Dholka on 21st July, 2015. Mr. Bhaginder Singh (AGM- QA) and Mr. Vijay Prajapati (AGM-Vaccine) imparted training to around 40 Pharma Cadilians. The objective of the training was to educate the participants about QMS which helps in consistent supply of high quality vaccines that are required for safeguarding people from infectious diseases. They discussed in detail about Deviation, Quality Risk Management, Investigation and CAPA.

Prior to conducting this session, Mr. Singh and Mr. Prajapati had attended a workshop on the same topic, organised by

Developing Countries Vaccine Manufacturer Network at Hyderabad. The learnings of the workshop were shared with the participants at the training program in Dholka.



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Among the 7 workshops, one was a pilot with only 22 participants, and two workshops were only two days long instead of 5 (see table below). All these efforts are partly supported by a grant from the Bill and Melinda Gates Foundation (Grant no. OPP 1113279)

Date	Location	Topic	Date Location Topic No. of participants at regional workshops (without trainers)	Follow-up trainees reported	Total participants benefiting per region
24-28 Nov. 2014	São Paulo	Risk Analysis & PQ	22	44	66
16-20 March 2015	Shanghai	Qualification & Validation and PQ	53	179	232
18-22 May 2015	Hyderabad	Qualification & Validation	57	197	254
6-10 July 2015	Rio de Janeiro	Quality, Qualification & Validation	38	114	152
3-4 August 2015	Beijing	Aseptic Processing & Cleanroom practices	67	70	137
7-8 October 2015	Bangkok	Quality by Design & PQ	84	n.a.	84
23-27 Nov. 2015	Hanoi	Gap, CAPA & environmental monitoring	91	54	145
Total			412*	658	1070

(*) according to our records only 25 individuals attended more than one workshop.

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General Manager of the Shanghai Institute of Biological products Dr. Zihou Yen welcoming the participants for a site visit



Rio training participants



Participants of the QMS workshop held in Hanoi, Vietnam in November 2015

Quality Vaccines for All People DCVMN annual meeting in Bangkok, Thailand



Prof. S. Khomvilai (QSMI) and Dr. J.-M. Okwo Bele (WHO)

The Developing Countries Vaccine Manufacturers Network (DCVMN) assembled high-profile leaders from global health organizations and vaccine manufacturers for its 16th Annual General Meeting, held from the 5th to the 8th of October 2015, in Bangkok, Thailand, to work towards a common goal: providing quality vaccines for all people.

Vaccines contribute to a healthy community and robust health system; the Ebola outbreak has raised awareness of the threat and damage one single infectious disease can make, and it is clear that the world was not prepared. However, more research to better understand emerging infectious agents may lead to suitable vaccines which help prevent future outbreaks.

DCVMN members presented their progress in developing novel vaccines against Dengue, HPV, Chikungunya, Cholera, cell-based influenza, and other vaccines, demonstrating the commitment towards eliminating and eradicating preventable diseases worldwide through global collaboration and technology transfer. The successful introduction of novel Sabin-IPV and Oral Cholera vaccine in China and Korea respectively in 2015 was highlighted.

Local health authorities and community leaders play an important role in the decision-making in vaccine introduction and up-take, based on the ability of vaccines to protect vaccinated people as well as protect non-vaccinated in the community through herd immunity. Reducing the risk of vaccine shortages can also be achieved by increasing regulatory convergence at regional and international levels.



Prof. Phan Wannamethee, Secretary General of the Thai Red Cross Society

Combating preventable diseases remains challenging, and collective efforts for improving vaccination were discussed including featured experts' panel discussions on the following topics:

- The power of multi-center international clinical trials,
- Developing regional vaccine security strategies,
- Fostering developing vaccine markets and procurement,
- Building trust in vaccines.

A two-day workshop concluded the enriching AGM, participants parted Bangkok informed and inspired to pursue their path towards the goal of eliminating preventable diseases.



Prof. Visith , QSMI

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Dr. J. Kim, (IVI)



Ms. A. Batson (PATH)



Panel discussion, from left to right: Mr. R.Mehta (Cadila), Ms. H. Deehan (UNICEF), Dr. M. Makhoana (Biovac), Dr. J. Kim (IVI), Mr. N. Prem Sri (Thai CDC/ASEAN) and Mr. T. Ibrahim (Arabio)



Ms. T. Jivapaisarnpong,
National Control Laboratory, Thailand



Mr. HT. Pham
BioNet-Asia



Mr. R. Prasad and
Dr. P. Khoury (right)



DCVMN Delegates

Governance statements

The Executive Committee receives, reviews, and approves reports from the Secretariat pertaining to the operations.

Meetings and teleconferences (TC) are structured with pre-set agenda items and relevant documents are circulated in advance to ensure the information is available where necessary to facilitate informed decision making. All voting Executive Committee members act on a voluntary, non-remunerated basis. In addition, DCVMN representatives appointed as senior advisers to the Executive Committee serve at the GAVI Board.

In 2015 there were 7 Executive Committee teleconferences on: February 15th, June 3rd, July 1st, August 19th, September 15th, November 10th and December 14th, and two face-to-face EC meetings held on April 13th and on October 5th. Participation of executive committee members is shown in the table below. Gavi Alliance Board representatives attended two Gavi Board meetings and one Gavi Board retreat within the calendar year.

At the general assembly on 06th October 2015, members approved the location of the next DCVMN AGM 2016, which will take place in Buenos Aires, Argentina, hosted by Sinergium Biotechnology.

Role	Name	Company	Attendance out of 7 TC/or meetings
President	Mr. Mahendra Suhardono	PT Biofarma	3
Vice-President	Mr. Rajinder K. Suri	Panacea Biotec	7
Treasurer	Dr. Akira Homma	Biomanguinhos	1
Member	Mr. Steven Gao	Innovax	4
Member	Ms. Li Meng	CNBG-Sinopharm	6
Member	Mr. Ray Prasad	Biological E	4
Member	Mr. Patrick Tippoo	Biovac	6
EC Senior Adviser (non-voting)	Dr. Suresh Jadhav	Serum Institute of India	5
Gavi Board Member (non-voting)	Mr. Adar Poonawalla	Serum Institute of India	1
Executive Secretary (non-voting)	Dr. Sonia Pagliusi	DCVMN International	7
Gavi board alternate (non-voting)	Mr. Juliman Fuad	PT BioFarma	

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Financial Statements

DCVMN International

Statement of Income and Expenditure for the year ended on 31st December 2015

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

BALANCE SHEET AS AT 31 DECEMBER

<u>ASSETS</u>	<u>2015</u>		<u>2014</u>	
	<u>CHF</u>	<u>USD</u>	<u>CHF</u>	<u>USD</u>
	@		@	
<u>Current assets</u>				
Cash	699'255.07 1.0010	698'556.51	844'698.82 0.9936	850'128.92
Investments	280'827.40 1.0010	280'546.85	0.00 0.9936	0.00
Advance for expenses	5'005.00 1.0010	5'000.00	4'968.00 0.9936	5'000.00
Receivables	0.00 1.0010	0.00	14'904.00 0.9936	15'000.00
Prépaid expenses	62'684.06 1.0010	62'621.44	2'702.19 0.9936	2'719.60
Total des actifs circulants	1'047'771.53	1'046'724.80	867'273.01	872'848.52
TOTAL ASSETS	1'047'771.53	1'046'724.80	867'273.01	872'848.52
<u>LIABILITIES</u>				
<u>Short-term liabilities</u>				
Payables	2'002.00 1.0010	2'000.00	3'768.35 0.9936	3'792.62
Accrued expenses	30'553.90 1.0010	30'523.39	2'750.00 0.9936	2'767.71
Total short-term liabilities	32'555.90	32'523.39	6'518.35	6'560.33
<u>Unrestricted reserves</u>				
Capital	860'754.66	928'014.57	286'724.37	308'016.20
Translation adjustment USD/CHF		-88'752.40		-61'726.38
Surplus	154'460.97	174'939.24	574'030.29	619'998.37
Total unrestricted reserves	1'015'215.63	1'014'201.41	860'754.66	866'288.19
TOTAL LIABILITIES	1'047'771.53	1'046'724.80	867'273.01	872'848.52

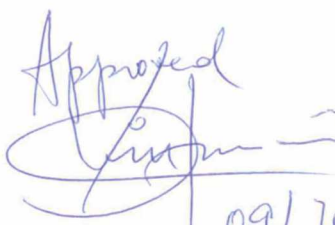
Approved,
Vincent
09 June 2016

DCVMN Annual Report 2015

DCVMN International
Developing Countries Vaccine Manufacturers Network
CH-1260 Nyon

INCOME AND EXPENDITURE STATEMENT FOR THE YEAR ENDED 31 DECEMBER

<u>INCOME</u>	<u>2015</u>		<u>2014</u>	
	<u>CHF</u>	<u>USD</u>	<u>CHF</u>	<u>USD</u>
			@	
Members contributions	281'473.50	290'000.00	216'926.10	237'000.00
Donations	494'062.20	521'000.00	432'432.93	472'437.39
Annual meeting contribution	57'778.88	60'375.00	52'629.75	57'500.00
Reimbursement meeting contribution	-2'529.29	-2'555.35	0.00	0.00
Annual meeting contribution participants	16'810.50	17'150.00	14'460.61	15'798.77
Other income	57.84	61.26	0.95	1.04
Foreign exchange gain	27'109.20	28'329.04	74'179.86	74'694.14
Total Income	874'762.83	914'359.95	790'630.20	857'431.34
 <u>EXPENDITURES</u>				
Salaries	106'188.35	109'322.30	98'558.65	107'679.10
Social contribution - AVS/AI/APG/AC/PCFam	9'110.45	9'418.70	7'775.60	8'807.06
Social contribution - Assurances	2'114.15	2'105.85	1'994.95	2'179.57
Social contribution - LPP	12'691.40	13'285.32	11'030.65	12'393.30
Office rental	6'529.33	6'709.60	3'877.20	4'256.94
Office insurance	343.35	367.26	381.45	416.75
Office supplies	1'456.30	1'508.18	1'734.93	1'900.13
Professional fees	13'073.00	13'474.90	6'077.00	6'744.57
Administration fees (salaries)	1'114.00	1'102.53	923.80	1'009.29
Website fees	0.00	0.00	4'244.40	4'637.17
Internal audit fees	3'004.25	3'001.25	0.00	0.00
Other administrative fees	0.00	0.00	2'170.90	2'371.79
Consulting fees (mock audit)	155'434.76	157'443.93	0.00	0.00
Training fees	243'144.57	251'919.54	14'627.30	15'980.88
Regulatory fees	27'632.80	28'240.09	0.00	0.00
Consulting Database fees	29'377.00	30'346.80	9'153.00	10'000.00
Publications fees	1'715.32	1'733.00	1'569.49	1'714.73
Meeting	4'322.92	4'535.93	0.00	0.00
Annual meeting	62'493.55	63'908.04	52'062.13	56'879.86
Miscellaneous fees	372.03	378.84	0.00	0.00
Loss on investments	12'729.09	13'138.26	0.00	0.00
Interests paid	0.00	0.00	125.15	141.40
Bank charges	5'437.29	5'440.30	863.31	943.19
Taxes on previous year	15'717.95	15'746.38	0.00	0.00
Taxes	6'300.00	6'293.71	-570.00	-622.76
Total expenditures	720'301.86	739'420.71	216'599.91	237'432.97
 SURPLUS	 154'460.97	 174'939.24	 574'030.29	 619'998.37

Approved

09/June/2016



Notes:

Over the year 2015, DCVMN has grown from 41 to 45 corporate members with four new manufacturers joining the network: Arabio, Bravovax, IMBCAMS (Institute of Medical Biology, Chinese Academy of Sciences) and VINS Bioproducts. DCVMN revenue has increased by 6.6%, from nearly 858 thousand USD to almost 915 thousand USD (see table). This was mainly due to fund raising activities and private donations, notably grant awards by the Bill and Melinda Gates foundation. DCVMN is moving towards a diversified and independent resources based on three main pillars: memberships, partnerships and donations, similar to many other international organizations, to achieve a sustainable and balanced operations' model. The number of corporate partners supporting our scientific education increased to 9.

At the last quarter of the calendar/financial year the network's activities and interim financial statements were presented by the executive committee to the general assembly of members, on October 06th, in Bangkok, Thailand, when the proposed 2016 activities and budget were approved by the assembly.

All income and disbursements are handled exclusively by bank transfer, providing independent and accurate accounting records complying with international accounting and business practices. All wirings are subject to two-signature system, prepared by the Secretariat and approved by the Treasurer, corresponding to bank transactions records and invoices to services, controlled by an external comptroller. All accounts were audited by an internal professional auditor nominated by the Executive Committee.

Of note, in 2015 the dollar valuation compared to Swiss franc has contributed to foreign exchange gain that reflects the value of the dollar on 31st December 2015 as compared to the average exchange rate of the dollar over the calendar year.

In income, subtitle "foreign exchange gain" materialized the difference between the exchange rate applied during the year and the exchange rate on 31st December 2015 according to the tax payable on 31st December 2015 revaluation rate.

Partnerships for Good

Global challenges, such as climate change, poverty reduction, economic globalization or the promotion and protection of human rights, combined with the emergence and re-emergence of infectious diseases over the last years, such as HIV/AIDS, TB, Ebola, have led to reshaping approaches to business.

Nowadays it is not enough to manufacture quality products and distribute them efficiently; society demands that corporations share social and environmental values with responsibility and accountability.

Corporate sponsoring is a form of Partnership between the private sector and governmental or non-governmental entities, in which the private sector entity enhances its corporate outreach, supporting an event or activity, through the provision of financial or in kind support, in exchange of visibility, and access to a wider community. Corporate sponsoring or donations activities are considered a subcategory of partnerships with the private sector and as such they may follow basic principles and guidelines applicable to international cooperation.

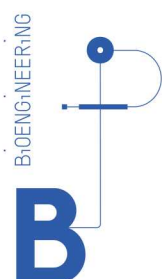
The benefits associated to partnerships for DCVMN, as a non-profit organization, include an increased ability to promote our social purpose with greater resources and strengthen best practices in emerging countries. Concomitantly, corporate partners benefit from an increased ability to reach other company's employees and customer base, bringing its business experiences and tools to new potential partners. These contributions are shared value and allow all involved parties to benefit from a mutual transfer of knowledge and skills, and enjoy a responsible corporate environment.

The UN has recommended organizations to set objectives for their partnerships with the private sector, with special attention to developing countries and countries in transition. DCVMN International represents a suitable platform for corporations to contribute to strengthening the vaccine supply capacity and doing good globally. We thank our generous partners for their loyal partnership!

Sonia Pagliusi
DCVMN Executive Secretary

Acknowledgments

To facilitate knowledge sharing and intensifying training opportunities for a skilled industry workforce, the annual meeting and regional workshops held in developing countries throughout 2015 were co-sponsored by corporate partners. We are grateful to corporate partners for helping foster manufacturing excellence for the benefit of all people.



We thank Queen Saovabha Memorial Institute from the Thai Red Cross Society, BioNet Asia for hosting and supporting the annual meeting, and the Bill and Melinda Gates Foundation for a conference Grant (grant no. OPP1135968).