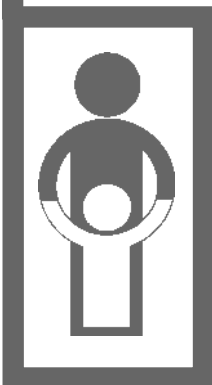


Fourth annual meeting of the Advisory Committee on Training (ACT)

Geneva, 23-24 February 1999



**DEPARTMENT OF VACCINES AND
OTHER BIOLOGICALS**



World Health Organization
Geneva
1999

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Contents

<i>Glossary</i>	<i>iv</i>
Executive summary	1
Progress	1
Policy, governance, and responsibilities	1
Follow-up, monitoring, and evaluation	1
Advocacy and fundraising	1
Further action required	2
Meeting report	3
Progress in the Global Training Network	3
Training center reports	4
Regional office reports	6
Policy issues	6
Follow-up, monitoring and evaluation	7
Discussions	8
Annex 1: Agenda	11
Annex 2: List of participants	13
Annex 3: Standard format for <i>curriculum vitae</i>	16

Glossary

ACT	Adisory Committee on Training
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé, France
BBR	Bureau of Biologics and Radiopharmaceuticals
BIRMEX	Gerencia General de Biologicos y Reactivos, Mexico
DTP	diphtheria-tetanus-pertussis (vaccine)
GMP	good manufacturing practice
GTN	global training network
IVP	International Children's Vaccine Training Program (Mass Labs), United States
LQS	lot quality systems
NIBSC	National Institute for Biological Standards and Control
NIID	National Institute of Infectious Diseases
NRA	national regulatory authority
RIVM	Rijksinstituut voor Volksgezondheid en Milieu, Netherlands
TGA	Therapeutic Goods Administration, Australia

Executive summary

Progress

There are now 12 certified Global Training Network (GTN) training centers around the world using certified course curricula. From a beginning in 1996 when one student was trained in a GTN placement course, and 1997 when there were two in placements, four in courses and 137 in workshops, the GTN has grown and placed 63 trainees in six courses, two in placements and 15 in workshops in 1998. Ten courses are scheduled so far for 1999, and the new proposed curricula for National Regulatory Authorities (NRAs) from vaccine procuring countries will begin in 1999. Two in-country follow-up workshops were just held to assess training impact. The GTN website provides up to date information on the GTN, the training centers and the courses.

Policy, governance, and responsibilities

The revision of the eligibility criteria for participation in GTN training courses will not be considered until the network centers and courses are well established. Regional offices will be assuming many of the responsibilities for applicant selection, funding of trainees, and performing assessments and follow-up of the regulatory authorities and manufacturers in their regions. In addition, the Regional Office for the Americas will assume the management the GTN courses and centers in the Latin American and Caribbean countries, coordinating this with headquarters staff. The potential for a steering committee to provide technical expertise for GTN, perhaps through more involvement of the Expert Review Panel members, will be explored.

Follow-up, monitoring, and evaluation

Three paths for assessing progress were discussed: course and trainee evaluations by the trainees and the training centers, respectively; distribution of proficiency panels for vaccine testing; and follow-up workshops at trainee institutions. All approaches will be continued. The utility of follow-up workshops for both trainers and trainees was clearly demonstrated in Egypt and Nigeria.

Advocacy and fundraising

Most available funding to support trainee costs has been transferred to the regional offices; thus, GTN funding from headquarters will generally not be available for trainees. Where possible, countries and applicants' institutions should contribute to training costs. Other sources of funding appropriate to the objectives of the GTN, should be actively sought.

Further action required

- The process of candidate selection will be refined to better match the students to the courses.
 - Brochures and course information will clearly state the types of applicants which are likely to benefit from the proposed training.
 - Information on the organizational structure and responsibilities of applicants will be obtained and considered in assigning students to courses.
 - To ensure equity and standard criteria, headquarters staff will select applicants, in consultation with regional offices, and forward applications to the training centers, who will make the final selection of applicants for training.
 - A standard format for curricula vitae which will better indicate scientific qualifications of candidates will be used.
 - Participation in laboratory quality control testing courses will be limited to candidates from active National Control Laboratories and Quality Control Laboratories of qualified manufacturing facilities.
 - For most countries, training should emphasize the “holistic” approach to vaccine regulation, and curricula that provide training in all the six functions will be increasingly useful.
 - The GTN secretariat will aim to inform countries of training courses at least three months in advance and to provide a list of proposed trainees to training centers at least one month prior to the start of the course.
- Model curricula, like those developed for the good manufacturing practice (GMP) and DTP production courses, should be developed for other courses given at more than one training site.
- Use of mechanisms to provide more technical input, perhaps involving members of the Expert Review Panels, will be explored. Already existing advisory committees to the Department of Vaccines and Other Biologicals can provide some of this input, including priorities for development.
- The proposed information brochure outlining the roles and responsibilities of the various players in the GTN will be finalized and circulated.
- Corrections to the recently updated application forms and institutional training plan forms will be made to indicate that the completed form must be sent through the WHO Regional Offices. The forms will be sent electronically to the regional offices.
- Training centers using their own application forms must ensure that the GTN application form and required supporting documents are also completed for each GTN trainee and routed through the appropriate regional office.
- Countries will be requested to consider investing in the training of their candidates.
- The GTN will explore new sources of funding, ensuring that support promotes the objectives of the GTN.

Meeting report

Dr Bjorn Melgaard, Director, Department of Vaccines and Other Biologicals, opened the meeting, explaining the goals of the Global Training Network, its progress, and its continuing relevance in the newly restructured World Health Organization.

Dr Jorge Gomez Herrera served as Chair and Dr Gillian Chaloner-Larsson as Rapporteur. The agenda of the meeting and the list of participants are provided in Annexes 1 and 2.

Progress in the Global Training Network

An update on activities of the GTN was presented by Dr Julie Milstien. She introduced GTN staff members working in Geneva: Mr Lahouari Belgharbi, serving as GTN co-ordinator, Ms Pascale Joseph, GTN manager, Ms Charlotte Mingle, GTN secretary, and Dr Gillian Chaloner-Larsson, a consultant providing technical support for curriculum development. Dr Milstien provided an update on progress in implementation of the recommendations of the Third ACT Meeting. The number of training centers and trainees has increased, and ten courses are scheduled for 1999 (Figure 1, Tables 1 and 2).

The impact of the GTN, however, is still measured by the ability of National Regulatory Authorities (NRAs) to perform the six essential functions and by the viability of public sector manufacturers, both contributing to use of vaccines of assured quality. This analysis shows that steady progress has been made in strengthening NRAs in vaccine-producing countries, and that an increasing proportion of public sector vaccine manufacturers are meeting viability criteria. However, countries not sourcing vaccines through local production have lagged behind in NRA development. Because of this, the need for a special curriculum for countries procuring vaccines was identified.

A brief description of this new curriculum for training NRA staff from vaccine procuring countries was presented by Dr Chaloner-Larsson. The course has been developed in three segments at different training centers on the four critical functions (licensing, United States of America; lot release and lab access, Canada; post-marketing surveillance, South Africa). The objective of the courses is to strengthen the NRAs from countries where direct procurement is the major vaccine source. A similar curriculum in Spanish is being developed in the Americas.

The recommendation of the Third Advisory Committee on Training to perform more in-depth country assessments has been followed, using performance indicators developed with input from 38 countries and refined at a meeting of an expert group convened in January 1999. Assessment visits, carried out in six countries in 1998,

are being supplemented by regional workshops devoted to this purpose, and, for vaccine procuring countries, specific assessment activities are included in procurement workshops.

In the discussions which followed the potential importance of new curricula at the Therapeutic Goods Administration (TGA), Australia, and the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France, which provide an overview of all NRA functions, was emphasized. It was considered that this type of training may be more relevant to most developing regulatory authorities, while the specific quality control testing courses would be more useful to staff of experienced laboratories.

Training center reports

Biken, Japan (Dr Suzuki): The activities of the Japan International Cooperation (JICA) Group Training Course in Vaccine Quality Control Technology were presented for 1995 to 1998 for DTP and Measles Quality Control Courses. Six students from six countries were trained in 1998: one in measles and five in DTP. The evaluation forms used by Biken were presented. An assessment visit was done with JICA in 1992; presently they are considering a questionnaire for follow-up. Although Biken's curriculum is certified by the GTN, none of the training given so far has been for GTN trainees.

National Institute for Biological Standards and Control (NIBSC), United Kingdom (Dr Phillips): Eight trainees from four countries were trained in Laboratory Quality Systems (LQS) in 1998. In addition, NIBSC ran a GTN LQS workshop for 15 trainees in the South-east Asia Region in September 1998. A key feature of the course is development by students of a proposed action plan to be implemented on their return. Follow-up activities have been e-mail contact to answer technical questions and an on site visit to Egypt in Feb 1999. Feedback from students indicates that the course needs to be more fundamental, and the course has been modified to reflect this. The revised curriculum has been submitted to the GTN for review.

BioFarma, Indonesia (Dr Marzuki): This Training Center held its first course in February 1999 on Quality Control of Measles and Polio Vaccines, sponsored by JICA. Dr Marzuki gave a summary of the training facilities, lecturers, trainees, and the application procedure. The course curriculum is certified by GTN but this session was not a GTN training course, as all applicants had not met GTN criteria. He concluded that more time is needed to organize the course through the GTN, and that WHO expert lecturers are still needed to complement the BioFarma lecturers.

National Institute of Infectious Diseases (NIID), Japan (Dr Masuda): Five courses ranging from one day to three months were held at NIID in 1998 on quality control methods. Twelve trainees from eight countries were trained but no training was provided for GTN trainees.

CECAL, FIOCRUZ, Brazil (Dr Andrade): The first GTN course was held in September-October, 1998. Twelve students working at animal facilities for the production and control of vaccines were trained in basic technical and practical knowledge in animal husbandry from Spanish and Portuguese speaking countries.

The main problems were logistic: receipt of funds and co-ordination of flight schedules. The next course was proposed for August 1999.

National Institute of Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu - RIVM), Netherlands (Dr Hendriks): A description of the policy of the Vaccine Technology Transfer and Training Centre and the organization of RIVM was given. Three GTN courses were given in 1998: DTP Production for Control Staff, Animal Husbandry, and Quality Control of DTP Vaccines. A brief description of each of the courses was given along with the proposed modifications to be made for 1999. One of each of these courses is planned for GTN for 1999. RIVM participated in the follow-up workshops in Egypt and Nigeria in February 1999. RIVM stated its desire to emphasize countries with which RIVM has technology transfer collaborations or plans for such collaborations in trainee selection, including both manufacturer and NRA staff from these countries.

BIRMEX, Gerencia General de Biologicos y Reactivos, Mexico (Dr Gomez): The presentation was a brief outline of the topics to be covered in the proposed GMP and Licensing courses, proposed as part of the new curriculum in the Americas for non-producing countries, planned for October 1999.

International Children's Vaccine Training Program (IVP), Massachusetts, United States (Dr Chaloner-Larsson): Four courses in GMP were given to 16 trainees in 1998. Three courses are planned for 1999. The first course will start in March. IVP also participated in the follow-up workshops in Egypt and Nigeria in February 1999, and has proposed a new curriculum for licensing for NRAs of vaccine procuring countries to start in the third quarter of 1999.

Therapeutic Goods Administration (TGA), Australia (Dr Walker): The training courses given by TGA were listed. TGA will be offering a course for vaccine-producing countries which covers all six functions of an NRA- It is planned for May 1999.

Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), France (Dr Fuchs): The background of the agency and its restructuring was explained, as well as their extensive training experience. Their GTN placement course in the six critical functions will increase GTN training opportunities for French speaking applicants. The outline of the course contents was presented.

Bureau of Biologics and Radiopharmaceuticals (BBR), Canada (Dr Bailey): The BBR presented its organization and functions. Their placement course for lot release and laboratory access for NRA staff from vaccine-procuring countries is presently under review.

University of Cape Town, South Africa (Dr Folb): A summary of the plans for the Training Programme on the Effective Management of Vaccine Safety Concerns was presented. The course, which is planned for five days, is aimed at developing the skills required to identify and competently deal with adverse events following immunization. The five-module course will include lectures and practical work on the role of regulatory authorities, immunization managers, national control laboratories, and national vaccine advisor groups. This course is under review.

Finlay Institute, Cuba (Dr Rios): This vaccine manufacturing facility described a proposed GMP course to be given in Spanish, including lectures and interactive techniques. Case studies will be included to make the course relevant for NRAs of vaccine-procuring countries.

Regional office reports

Mr OA Oni, African Region, gave a summary of the present status of NRA functions in Africa, priorities for training in 1999, and projections for improvement in the critical functions for 1999 and 2000.

Dr Otavio Oliva, Region of the Americas, presented the background of training and GTN priorities for Latin America and the Caribbean. There are six training centers in the Americas training in GMP, animal husbandry, Laboratory Quality Systems, and DTP production. They will soon be introducing a course in licensing and lot release. They presented plans for 1999 courses and the funds obtained for 1999.

Mr Belgharbi reported on activities in **Eastern Mediterranean Region.** He included information on the impact of GTN in their vaccine quality activities, explaining the situation before GTN and the progress made. The budget and results of successful fundraising from the Islamic Development Bank were presented. Constraints in this region are the time it takes to process applications, and the inconsistency of local support and expertise. In addition the post of vaccine quality focal point at EMRO has been abolished.

Dr Cato de Savigny, South-East Asia Region, gave a summary of their present staff for GTN activities, a breakdown of their total vaccine related activities, budget for 1998, trainees trained in 1998 (23 trainees from six countries at six training centers), and plan of action for 1999.

Ms Susan Shin, Western Pacific Region, gave a rundown of the activities, budget, and distribution of costs for 1998 and a summary of 1995-1998 initiatives.

The second day of the meeting covered policy issues, monitoring, follow-up and evaluation, and advocacy and fundraising.

Policy issues

Candidate selection (Dr Milstien): More information on the applicants is needed and the application forms have been changed to get some of that information. While there should be more involvement by the regional and country offices in screening and prioritizing applicants, headquarters GTN staff will submit applicants to the training centers, in order to optimize geographical balance across regions and to ensure standardization of selection criteria. Direct telephone interviews by the regional offices could be used to determine language ability. There was general agreement that after six trainees from one country had attended courses at different centers, a follow-up workshop should be planned for staff of the trainee institution(s).

Regional resources for the GTN (Mr Belgharbi): A description of the personnel, operational units, and financial resources available at the regional level was provided. The interactions between headquarters and the potential for devolving GTN responsibilities to the regions, in particular obtaining funds, making the initial institutional assessments, candidate screening and prioritization were also presented.

Communications (Dr Milstien): A description of the extent of lines of communications among headquarters staff, the regional offices, the training centers, the applicants and their institutions to keep the GTN in operation was presented, along with many queries about the utility and appropriateness of some of the communication links. It was generally agreed that applicants should be sent through the WHO GTN system. Any direct applications received at the training centers should be referred to the appropriate regional office. It was agreed that links between training centers should be promoted, as should links between trainees, but no definitive mechanisms as to how this could be accomplished were proposed. Communications with the Expert Review Panels members was also discussed, questioning whether they should be more actively involved in the GTN or remain solely as advisors on course curricula. More comments on these issues were solicited from ACT participants.

Information Brochure (Dr Chaloner-Larsson): A draft proposal of an information brochure was presented to find out if the ACT participants thought such a leaflet would be useful in defining the roles and responsibilities of the various players in the GTN. Certain improvements were needed in the draft, but the idea was agreed to be a good one. It should be developed taking into account the lines of communication described and discussed, and the increased role of the regional offices. It will be revised and circulated to the ACT participants. The recently revised GTN forms were also briefly reviewed and several inconsistencies will be corrected. The forms will be provided electronically to the regional offices.

Follow-up, monitoring and evaluation

Summary of the GTN assessment forms (Ms Joseph): A summary of the comments made by trainees and by trainers on the course content and suitability of trainees was presented by Pascale Joseph. The most frequent responses were discussed and an anonymous list of comments on each course was circulated. Generally, the topics presented in all courses were considered appropriate, some were insufficiently covered, and most courses were considered the right length. The greatest number of similar comments came from the GMP course for NRAs. Many trainees thought more emphasis was needed on regulatory affairs and NRA activities. Training centers thought candidate selection should be improved, and trainees should be made more aware of the content of the courses.

Progress on proficiency testing (Dr Phillips): Last year's ACT meeting decided that proficiency panels for testing capabilities should be planned and carried out by NIBSC for pertussis and measles potency with clear pass and fail samples. Dr Phillips reported on the status of this recommendation. The measles material has been sourced and a draft protocol for the measles study has been circulated with 16 manufacturers and national control laboratories agreeing to take part. The study materials will be sent out in the first week of March. The laboratories will remain anonymous in the report which will be circulated to all participants. Sources of clear pass and clear fail

materials for the pertussis potency test proficiency panel are being investigated by WHO. After the first round of testing, designed to standardize the methodology, a second round will be initiated to include laboratories of trainees.

Follow-up activities in Egypt and Nigeria (Dr Milstien): Follow-up workshops held in February 1999 were with the participation of GTN headquarters and regional office staff and representatives from three training centers: NIBSC, RIVM and IVP. The teams were impressed with the progress and found that this kind of follow-up was very rewarding both for the trainers and trainees and their respective institutions. Needs and priorities for NODCAR (Egyptian NCL) and NAFDAC (Nigeria NCL) were identified for each of the six critical control functions.

Financing: Status, sources, and long-range planning (Dr Milstien): The report included GTN expenditures for 1998 (see Table 3), amounts of money transferred to the regions for GTN activities (Table 4), the sources of funding at headquarters, region and trainee levels, and the future needs to raise more money. More money should be provided for the trainees from their own institutions and their countries, including WHO country budgets, supplemented by regional funds. Efforts are needed for the regions to try to raise funds from new sources which are supportive of GTN objectives. International Vaccine Institute in Korea and the African Development Bank were suggested.

Discussions

The discussions on the second day of the meeting highlighted two issues. Candidate selection was discussed in depth and it was decided that perhaps two lines of focus for training could be followed: specific laboratory courses for applicants from active laboratories in National Control Laboratories or qualified manufacturers, and a more "holistic" overview approach that would cover all aspects of the relevant critical functions to train leaders of the NRAs. The scientific qualifications of those trained for laboratory and NRA work was raised and the possibility of defining the content of the applicant's curriculum vitae was considered and agreed (See Annex 3).

The second important issue was the question of revising selection criteria for GTN training courses (currently trainees must be staff of NRAs or of qualified manufacturers; the proposal was to remove the need for qualification of manufacturers). Several ACT members thought this could be done without compromising the GTN objectives. However, several active training centers with GTN certified curricula have not yet given courses for GTN applicants, but have agreed with the policy. It was decided that it was premature to change the criteria until the GTN is better established and the impact of policy changes can be better evaluated.

Figure 1: Current status, 1999

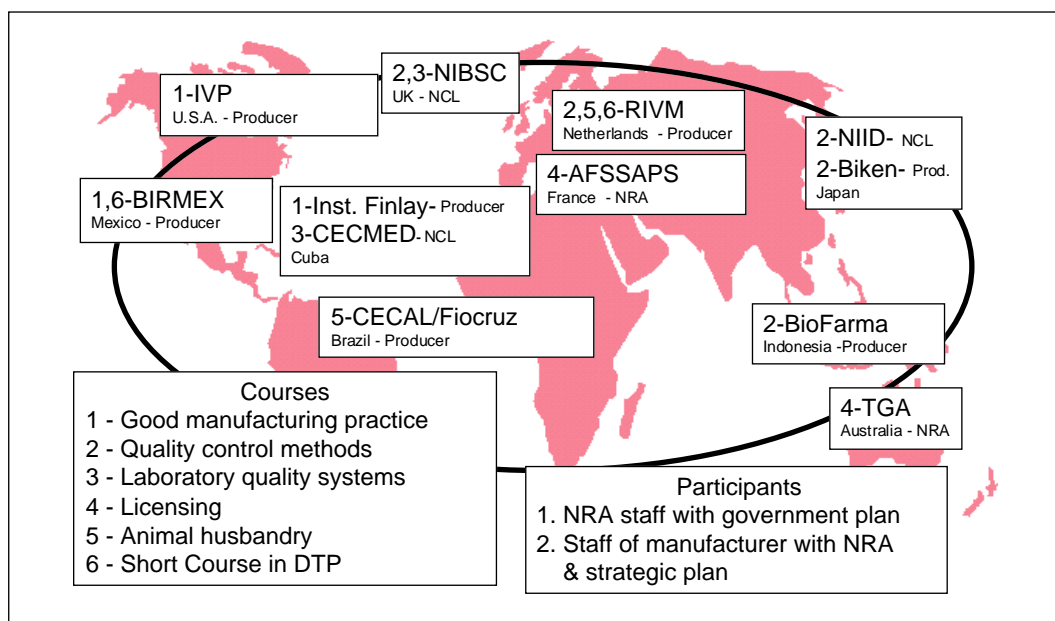


Table 1: Trainees in the Global Training Network, 1996-1998

Year	Courses	Placements	Workshops	Total
1996	-	1	-	1
1997	4	2	137	143
1998	61	2	15	78

Table 2: Global Training Network 1999 – Course schedule

Subject	Site	Date
QC testing (measles, OPV)*	Bio Farma	7 February - 10 March 1999
DTP production for control staff	RIVM	22 March - 2 April 1999
GMP	IVP	22 March - 10 April 1999
Lab quality systems	NIBSC	12 April - 14 May 1999
Licensing	TGA	5 - 12 May 1999
DTP production for control staff (Spanish)	BIRMEX	7 - 11 June 1999
Laboratory animal science and husbandry in vaccine quality control	RIVM	6 - 17 September 1999
Quality control of DTP vaccines	RIVM	1 - 26 November 1999
GMP (Spanish)	SIREVA	To be determined
Lab quality systems (Spanish)	SIREVA	To be determined

Table 3: Expenditures for 1998

Category	Amount in US\$
Global coordination	360 991
Assessments	47 328
Meetings	58 486
Workshops	52 917
Documents	50 982
Training costs	421 353
Follow-ups	34 605
Transfer to WHO regions	1 177 536
TOTAL	2 204 198

Table 4: Amounts transferred to WHO regions

WHO regional office	Amount in US\$
Regional Office for Africa	250 000
Regional Office for the Eastern Mediterranean	300 000
Regional Office for South-East Asia	357 036
Regional Office for the Western Pacific	270 500
TOTAL	1 177 536

Annex 1: Agenda

Tuesday, 23 February 1999

- 09:00** Opening of the Meeting
Welcome by Dr Michael Scholtz, Executive Director,
Health Technology and Pharmaceuticals Cluster (HTP)
Administrative announcements
Selection of Chair and Rapporteur
Introduction of participants
- 09:30** Progress in the Global Training Network
Update on activities since last meeting
New curriculum on procurement
Discussions
- 10:30* *Coffee*
- 11:00** Reports from training centers (5 minutes each)
1. BIKEN, Japan
 2. National Institute for Biological Standards and Control (NIBSC)
 3. BioFarma, Indonesia
 4. National Institute of Infectious Diseases (NIID), Japan
 5. CECAL/FIOCRUZ, Brazil
 6. Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Netherlands
 7. Gerencia General de Biologicos y Reactivos (BIRMEX), Mexico
 8. International Children's Vaccine Training Program (IVP – Mass Labs), USA
 9. Therapeutic Goods Administration (TGA), Australia
 10. Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
 11. Bureau of Biologics and Radiopharmaceuticals (BBR), Canada
 12. University of Cape Town
 13. Finlay Institute
- 12:30* *Lunch*

Tuesday, 23 February 1999 *(continued)*

- 14:00** **Discussion of training activities**
- 15:30* *Tea*
- 16:00** **Reports from the WHO Regions (10 minutes each)**
- African Region**
- Region of the Americas**
- Eastern Mediterranean Region**
- South-East Asia Region**
- Western Pacific Region**
- 17:30** **Adjourn**

Wednesday, 24 February 1999

- 8:30** **Policy issues**
- Candidate selection
 - Regional resources for GTN
 - Communications
 - Information brochure
 - Discussion
- 10:30* *Coffee*
- 11:00** **Progress on follow-up, monitoring, and evaluation**
- Review of the responses in the Assessment Forms
 - Progress on proficiency testing
 - Report on follow-up activities in Egypt and Nigeria
- 12:30* *Lunch*
- 14:00** **Follow-up, monitoring and evaluation: discussion**
- 15:30* *Tea*
- 16:00** **Financing: status, sources, and long-range planning**
- General discussion of issues and plan for 1999**
- 17:00** **Summary and conclusions**
- 17:30** **Adjournment**

Annex 2:

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Annex 3:

Standard format for *curriculum vitae*

- Part 1. Details of scientific, medical, veterinary qualifications: Type of degree with dates of award and awarding institution
- Part 2. Laboratory experience in virology, bacteriology, immunology or similar area
- Part 3. Supervisory or management experience
- Part 4. Experience in regulatory work including laboratory testing of products, tests (*in vitro* and *in vivo*) undertaken, protocol review, license review
- Part 5. Research experience related to biologicals
- Part 6. Specify products currently controlled by the candidate's institution. What tests are currently being undertaken on these products?