

STATUS OF GOOD LABORATORY PRACTICE (GLP) IN SOUTH AFRICA

By Shadrack Phophi

The OECD Principles of Good Laboratory Practice (GLP) are a managerial quality control system covering the organisational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded and reported. The OECD Principles of GLP are followed by *test facilities* carrying out studies to be submitted to national authorities for the purposes of assessing the health and environmental safety of chemicals and chemical products which may also be of natural or biological origin and, in some circumstances, may be living organisms. Depending on the jurisdiction, the Principles of GLP can also be applied to non-clinical safety testing of other regulated products, such as medical devices.

In South Africa, national authorities or receiving authorities responsible for the registration of chemicals are the Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health (DoH) and both these departments they do not legislatively mandate test facilities that conduct non-clinical health and environmental safety studies to comply with GLP. Test facilities that are currently SANAS GLP compliant have done so on their own volition and/or due to client demand. Consequently, the GLP programme will remain being one of the smallest programmes within SANAS for the foreseeable future until such time that the two national authorities or receiving authorities make GLP mandatory for test facilities that conduct non-clinical health and environmental safety studies.

Recently, however there has been an upsurge of enquiries regarding GLP compliance especially from the facilities that are in the Pesticide industry. The sudden interest apparently is due to the possibility of DAFF legislatively mandating all residue studies to be conducted in accordance with GLP as from 2018. If DAFF goes ahead with the plan of mandating test facilities that perform residue studies to do so in accordance with GLP, the program is likely to grow by at least 5% in the next 12 months. Currently, SANAS has granted GLP compliance to only 8 facilities. Of the 8, one is a foreign research facility that conducts malaria related studies.

SANAS is the only GLP Monitoring Authority (MA) in the country and of course the only one in the entire continent. Accordingly, the London School of Hygiene & Tropical Medicine through its non-profit organisation Innovative Vector Control Consortium and together with its partners has designated SANAS as the preferred MA to inspect 6 Malaria research sites in the African continent. These sites are based in 4 different countries, namely: Tanzania, Benin, Burkina Faso and Ivory Coast. This move followed the World Health Organization (WHO) announcement that it will start require all malaria studies conducted over 14 research sites across six regions to be conducted in accordance with GLP (see details in the table below). According to WHO, compliance to OECD principles of GLP enhances the quality and reliability of research data and it also significantly reduces delays associated with registration of much needed malaria control vector products.



REGION	SITES
West of Africa	<ul style="list-style-type: none"> Institut Pierre Richet (IPR), Institut National de Santé Publique, Cote d'Ivoire Institut de Recherche en Sciences de la Santé (IRSS) Centre Muraz, Bobo Dioulasso, B.F. CREC, Cotonou (in collaboration with LSHTM), Benin Centre Suisse de Recherches Scientifiques en Cote d'Ivoire, CSRS, Cote d'Ivoire
East Africa	<ul style="list-style-type: none"> Kilimanjaro Christian Medical University College, Moshi, Tanzania Ifakara Health Institute, Bagamayo Research & Training Centre, Tanzania
Americas	<ul style="list-style-type: none"> Brazil & any other Latin American institution (TBD) Centro Regional de Investigación en Salud Pública, Tapachula, Mexico
Western Pacific	<ul style="list-style-type: none"> Vector Control Research Unit, Universiti Sains Malaysia, Penang, Malaysia Institute for Medical Research, Kuala Lumpur, Malaysia WHO CC – Centre for Disease Control, Beijing, China
SEA	<ul style="list-style-type: none"> WHO CC – National Institute of Malaria Research (NIMR), Delhi, India WHO CC – Vector Control Research Centre, Puducherry, India
European	<ul style="list-style-type: none"> WHO CC – IRD, Montpellier, France

SOUTH AFRICA TO HOST THE 2019 OECD GLP TRAINING COURSE

The OECD GLP Working Group of which South Africa through SANAS is part of has officially nominated South Africa as the host of the GLP training course in 2019. The GLP training course has been running since 1990, thus, the 2019 training is going to be the

14th edition. Since its inception, 11 countries had the privilege of hosting the GLP training course. Of the 11 countries, only 4 were from outside Europe. The table below shows the history of countries who have hosted training courses to date.

Date	Country	Course	Geographical region
Jan 1990	France	Basic	Europe
May 1992	Netherlands	Basic	Europe
Jun 1994	US	Advanced (field study)	North America
Nov 1996	UK	Advanced (computer system)	Europe
Apr 1999	Italy	Advanced (study audit)	Europe
Mar 2002	US	Basic	North America
Apr 2004	Belgium	Advanced (multi-site study)	Europe
Sep 2006	UK	Basic	Europe
Oct 2009	Switzerland	Basic	Europe Non-EU
Oct 2011	Israel	Advanced (study audit)	Middle East
Oct 2013	Japan	Advanced (IT and Test item?)	North East Asia
Oct 2015	India	Advanced	South Asia
Oct 2017	Poland	Advanced	Europe

South Africa made history in 2002 to be the first non-OECD member country to be accepted as full-adherent to the GLP Mutual Acceptance of Data (MAD). The MAD was opened up to non-OECD members in 1997 and since the acceptance of South Africa as a full-adherent, 5 more non-OECD members joined the MAD namely: Argentina, Brazil, India, Malaysia and Singapore. Once again, South Africa will make history by being the first African country to host the OECD GLP training course in 2019.

For the training, OECD countries and full adherent countries are apportioned at least 2 spaces for trainees. Thus, if the past trend is anything to go by, South Africa can expect to host not less than 60 trainees from both the OECD and full adherent countries.

CONTACT INFORMATION

SANAS website: www.sanas.co.za | **Main Switchboard No:** +27 (0) 12 394-3760 | **General Fax No:** +27 (0) 12 394-0526 |
Physical Addresses: the dti Campus, Block G, Ground Floor | 77 Meintjies Street, Sunnyside, Pretoria | **SANAS Knowledge Transfer Centre:** 121 Muckleneuck Street Nieuw Muckleneuk | Pretoria | 0002 | Private Bag X23 | Sunnyside | Pretoria | 0132

