ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES

CAB Accreditation Advisory Document

Document Title: **Advisory Document on ACCAB Good Laboratory Practice (GLP) Conformity Recognition Programme**

Document Number: **ACCAB-CAB-AD-8.0**

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Revision Number	Revision Date	Paragraph Number	Description of Revision	Revision Author

AD-8.1	**Purpose:**
AD-8.1.1	The World Trade Organization (WTO) 's Committee on Technical Barriers to Trade takes a position that the objective of Conformity Assessment (CA) is to provide the parties with sufficient trust and confidence for commerce to occur. It further states that CA provides: • A way for consumers (and regulators) to gain confidence in the products and services offered by suppliers and differentiate between them; • A way for legitimate suppliers to build confidence in their products or services and differentiate themselves from competitors; • And this "process" – known as Brand Building – is critical to business survival because it ensures ongoing commerce.
AD-8.1.2	This advisory note makes a sincere attempt to put forward neutral information about ACCAB Good Laboratory Practice (GLP) Conformity Recognition Programme without any commercial bias.
AD-8.2	**Scope:**
AD-8.2.1	This advisory note is published for the informative use for the all ACCAB Accreditation Regime Stakeholders such as Laboratories seeking ACCAB GLP Conformity Recognition , Private and Public Enterprises, Government Departments & Agencies, Trans National organizations, NGOs and the Global Communities of Businesses and Consumers.
AD-8.3	**Details:**
AD-8.3.1	**About OECD:**
AD-8.3.1.1	The Organization for Economic Cooperation and Development (OECD) is a unique forum where the governments of 34 democracies with market economies work with each other, as well as with more than 70 non-member economies to promote economic growth, prosperity, and sustainable development. The Organization provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and coordinate domestic and international policies. As per OECD it has 34 members. Please refer the link for OECD members: http://www.oecd.org/about/membersandpartners/list-oecd-member-countries.htm
AD-8.3.2	**Introduction to GLP:**
AD-8.3.2.1	Good Laboratory Practice is a Quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. However, having GLP recognition does not affirm the technical validity of these studies. The studies are undertaken to generate data by which hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, pesticides, cosmetics, veterinary drugs, feed additives, food additives and industrial chemicals. GLP helps assure stakeholders that the data submitted are true reflection of the results obtained during the study and can

	therefore be relied upon when making safety assessments.
AD-8.3.2.2	The Principles of GLP are applied to studies conducted for non-clinical health and environmental safety studies of test items contained in various chemical products. A study covers work done in a laboratory, animal house, greenhouses and in the field. Non-clinical studies may cover physical-chemical testing, toxicity studies, mutagenicity studies, environmental toxicity on aquatic and terrestrial organisms, studies on behaviour in water, soil and air; bioaccumulation, residue studies, studies on effects of mesocosms and natural ecosystems and the analytical chemistry associated with such studies.
AD-8.3.2.3	The claimed purpose of GLP is to promote the quality and validity of data generated in the testing of chemicals, facilitate their recognition , avoidance of duplicative testing , protection of human health & environment , animal welfare , time and resource efficiency and **avoidance of non-tariff barriers to trade**.
AD-8.3.3	**Is GLP Mandatory:**
AD-8.3.3.1	OECD non- member countries like Brazil, India, Malaysia, and Singapore have GLP voluntary program. However in some countries, particularly those within European Union it is required by law that any non-clinical studies are to be conducted in compliance with the OECD Principles of GLP.
AD-8.3.4	**OECD Mutual Acceptance of Data (MAD):**
AD-8.3.4.1	The OECD on its website states that and this document quotes:
AD-8.3.4.1.1	The testing of chemicals is labour-intensive and expensive. Often the same chemicals are being tested and assessed in several countries. The OECD Council therefore adopted a Council Decision* in 1981 – on Mutual Acceptance of Data (MAD) - stating that test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.
AD-8.3.4.1.2	A further Council Act was adopted in 1989 to provide assurance that the data are indeed developed in compliance with the Principles of GLP. This Council Decision-Recommendation on Compliance with GLP establishes procedures for monitoring GLP compliance through government inspections and study audits as well as a framework for international liaison among monitoring and data-receiving authorities.
AD-8.3.4.1.3	A 1997 Council Decision on the Adherence of Non-Member countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals sets out a step-wise procedure for non-OECD countries to take part as full members in this system.
AD-8.3.4.1.4	*There are two types of Council Act. A Council Decision, which is legally binding on OECD Member countries, and a Council Recommendation, which is a strong expression of political will.
AD-8.3.5	**EU Directive 2004/10/EC:**

AD-8.3.5.1	DIRECTIVE 2004/10/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) , Article 5 1. states where Community provisions require application of the principles of GLP following the entry into force of this Directive for tests on chemical products, Member States may not, on grounds relating to the principles of GLP, prohibit, restrict or impede the placing on the market of chemical products if the principles applied by the laboratories concerned are in **conformity** with those mentioned in Article 1.
AD-8.3.6	**US FDA Guidance For Industry of GLP :**
AD-8.3.6.1	According to the published US FDA Guidance note, US FDA does not reject nonclinical laboratory studies that have not been conducted in full compliance with the GLPs. The GLP Compliance Program provides guidance on the issue. For US FDA to reject a study, it is necessary to find that there were deviations from the GLPs and that these deviations were of such a nature as to compromise the quality and integrity of the study covered by the agency inspection.
AD-8.3.7	**ACCAB GLP Conformity Recognition Programme:**
AD-8.3.7.1	Accreditation Commission for Conformity Assessment Bodies (ACCAB) is an Independent, International Accreditation Body (AB). It works to serve the global communities of businesses and consumers. ACCAB accredits appropriately qualified independent third party Conformity Assessment Bodies (CABs) such as Certification Bodies, Inspection Bodies, Testing & Calibration Laboratories and Medical Laboratories to ensure that their competence to carry out specific tasks is as per the International Standards & the Benchmarks. ACCAB GLP Conformity Recognition Programme is voluntary in nature.
AD-8.3.7.2	The authority vested is ACCAB is that assigned to them by the Conformity Assessment Bodies and other Organization it accredits and recognizes by virtue of these applicant and accredited bodies pledging support for the mission and objectives of ACCAB and ensuring that their actions are according to that policy. It is an independent, impartial and non-governmental body and makes no claim to be connected with any government.
AD-8.3.7.3	ACCAB deploys polices and procedures as per ISO 17011 with respect to it Conformity Assessment Accreditation / Recognition Programmes. Assumption or presumption of the applicability of ACCAB GLP Conformity Recognition Programme is solely drawn by and at the discretion of parties who may find this programme beneficial.
AD-8.3.7.4	ACCAB GLP Conformity Recognition Programme requires that a test facility seeking Recognition for Conformity with the OECD GLP Principles should apply for ACCAB GLP Assessment in a prescribed format, stating its proposed scope of recognition and type of studies, providing key information such as Master Schedule of Studies, Floor Plan, Organisation and Test Facility Structure, Key responsibilities of the personnel and units, Information of Study Sponsor, Curricular Vitae of test

	facility/ Personnel, Quality Manual, Standard Operation Procedures Structure and others relevant document. The management of test facilities must issue a declaration, where applicable, that a study was carried out in accordance with GLP Principles and pursuant to any other provisions established by national legislation or administrative procedures dealing with good laboratory practice.
AD-8.3.7.5	ACCAB GLP Conformity Recognition Programme is provided on an "as is" without warranties of any kind, either express or implied.
AD-8.3.7.4	To know about ACCAB GLP Conformity Recognition Programme Certificate, please check below referred documents of ACCAB origin or contact ACCAB at info@accab.org
AD-8.4	**References:**
AD-8.4.1	World Trade Organization.
AD-8.4.2	**OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring.**
AD-8.4.3	Guidance for Industry - Good Laboratory Practices Questions and Answers, published by US FDA.
AD-8.4.4	Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substance.
AD-8.4.5	Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP).
AD-8.4.6	ACCAB Digital Brochure GLP
AD-8.4.7	ACCAB-FC-H-Conformity Recognition Programme Process Flowchart-GLP
AD-8.4.8	ASM-6.0-Introduction to ACCAB
AD-8.4.9	ASM-7.0-Various Accreditation Schemes
AD-8.4.10	ASM-8.0-F-01-H- ACCAB R F Q Conformity Recognition Programme of GLP
AD-8.4.11	ASM-8.0-L- Accreditation Procedure for Laboratories
AD-8.4.12	ASM-9.0-Accreditaion Requirements
AD-8.4.13	ASM-11.0-H-ACCAB Schedule of Fees for GLP
AD-8.4.14	ASM-14.0-H- ACCAB Conformity Recognition Programme Application Form-GLP