Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO
Swiss Accreditation Service SAS

SIS Directory

Accreditation number: SIS 0121

International standard:	ISO/IEC 17020:2012
Swiss standard:	SN EN ISO/IEC 17020:2012

Swissmedic
Swiss Agency for Therapeutic Products
Inspectorates
Hallerstrasse 7
3012 Bern

Head:	Dr. Christian Schärer
Responsible for MS:	Dr. Roel op den Camp
Telephone:	+41 58 462 01 17
E-Mail:	roel.opdencamp@swissmedic.ch
Internet:	http://www.swissmedic.ch
Initial accreditation:	07.07.2006
Current accreditation:	07.07.2021 to 06.07.2026
Scope of accreditation see:	www.sas.admin.ch (Accredited bodies)

Scope of accreditation as of 29.03.2023

Inspection body (Type A) for manufacturers and distributors of medicinal products and Advanced Therapy Medicinal Products (ATMP) according to GMP and GDP directives

Standards	Approved technical scopes	Remarks
INTERNATIONAL STANDARDS		All inspections are defined in the internal directive 305.RL.01
Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use	Manufacture and testing*) of medicinal products for human use	
Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products	Manufacture and testing*) of veterinary medicinal products	

SIS Directory

Accreditation number: SIS 0121

Standards	Approved technical scopes	Remarks
Guide to good manufacturing practice for medicinal products for human use and medicinal products for veterinary use of the European Commission (EudraLex, Volume 4)	Manufacture and testing*) of medicinal products	
Principles and Guidelines for good manufacturing practice in accordance with the convention for the mutual recognition of inspections in respect of the manufacture of pharmaceutical products of 8 October 1970	Manufacture and testing*) of medicinal products	The PIC/S requirements are, with some EU specific exceptions, identical to the EU Guide to good manufacturing practice for medicinal products for human use and medicinal products for veterinary use
Guidelines of the European Commission of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)	Distribution of medicinal products for human use	
Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)	Distribution of API for human medicinal products	
Measures on good distribution practice for veterinary medicinal products, Regulation (EU) 2021/1248	Distribution of medicinal products for veterinary use	
Measures on good distribution practice for active substances used as starting materials in veterinary medicinal products, Regulation (EU) 2021/1280	Distribution of API for veterinary medicinal products	
Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community	Manufacture of medicated feeding stuffs	
Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed	Distribution of medicated feeding stuffs	
European Pharmacopoeia	Manufacture, processing, testing*) and trade of medicinal products	

SIS Directory

Accreditation number: SIS 0121

Standards	Approved technical scopes	Remarks
Good Practice Guidelines, according to the annex of the Recommendation R (95) 15 of the Council of Europe dated 12 October 1995 on the preparation, use and quality assurance of blood components	Collection, processing, storage and distribution of blood and blood components	
Recommendation R (95) 15 of the Council of Europe dated 12 October 1995 on the preparation, use and quality assurance of blood components (including Appendices	Selection and information of donors of blood and blood components	
Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC	Collection, processing, storage and distribution of blood and blood components	
Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	Collection, processing, storage and distribution of blood and blood components	
Commission directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events	Traceability of blood and blood products	
Commission directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council with regard to Community standards and specifications relating to a quality system for blood establishments	Collection, processing, storage and distribution of blood and blood components	
NATIONAL STANDARDS		
Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21)	Manufacture, testing*) and distribution of medicinal products	

SIS Directory

Accreditation number: SIS 0121

Standards	Approved technical scopes	Remarks
Products Licensing Ordinance of 14 November 2018 (MPLO; SR 812.212.1)	Manufacture, testing*) and distribution of medicinal products	
Federal Act of 8 October 2004 on the transplantation of organs, tissues and cells (Transplantation Act, SR 810.21)	Manufacture, testing*) and distribution of transplant products	For transplant products (in the sense of ATMP), the identical standards as for medicinal products are applicable.
Pharmacopoea Helvetica	Manufacture, processing, testing*) and trade of medicinal products	

*) *Note:* The term „testing“ in the approved technical scopes refers to the inspected activities and does not refer to the activities performed by the inspection body.

In case of contradictions in the language versions of the directories, the German version shall apply.

Abbreviation	Signification
ATMP	Advanced Therapy Medicinal Products (see www.swissmedic.ch/ATMP-en)
EC	European Community
EEC	European Economic Community
EU	European Union
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
SR	Classified Compilation of Federal Law

* / * / * / * / *