Crosswalk between EU Annex 11 and US FDA – 211, 820, 11; other guidelines and regulations

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	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
Principle. (Data quality element: Acurate)					GAMP 5 –Management Appendix M3. Data quality element: Accurate.
a. This annex applies to all forms of computerised systems used as part of a GMP regulated activities. A computerised system is a set of software and hardware components which together fulfill certain functionalities.		211.68[1]	820.70(i).	11.2(b).	EU Directives 2017/1572 and 91/412/EEC. PIC/S PI 011-3. ISO 13485 7.5.2. Article 1 draft Annex 2 CFDA GMP. OECD Guidance Document, Section 1.1.1. 211.68(a)
b. The application should be validated; IT infrastructure should be qualified.	11-3	211.68	820.70(i). 820.30(g) 820.170	11.10(a).	Eudralex Volume IV, Glossary PIC/S PI 011-3. ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Sections 5.40 and 5.41. WHO - Technical Report Series, No. 937, 2006. Annex 4. Appendix 5, Section 7.1 (Hardware). ISO 13485 7.5.2; 7.3.6; 7.2; 7.2.1; 7.2.2 Article 10 draft Annex 2 CFDA GMP. GAMP GPG: IT Infrastructure

[1] O. López, "*A Historical View of 21 CFR Part 211.68*", Journal of GXP Compliance, Vol. 15 No. 2, Spring 2011.

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	References				
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					Control and Compliance, 2005. OECD Guidance Document, Section 1.1.2. ICH E6 Guideline for GCP (June 1996), Section 5.5.3(a) ANMAT (Argentina) 5.21 US FDA General Principles of Software Validation, Section 5.2.6. Part II - Basic Requirements for Active Substances used as Starting Materials, Section 5.40. Sections 8.1 and 9.10 Russian Federation DI Guideline Health Canada GMP Guidelines C.02.05 – 8.f.i. MHRA, Sections 9.2; 9.3 #2, #6
c. Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.	Principle				PIC/S PI 011-3. US FDA CPG 7348.810 - Sponsors, CROs, and Monitors. Thailand CSV GMPs. Article 2 draft Annex 2 CFDA GMP.

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	References				
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General.					
1. Risk Management. Risk management should be applied throughout the lifecycle of the computerised system considering patient safety, data integrity and product quality. As part of a risk management system, decisions on the extent of validation and data integrity controls should be based on a justified and documented risk assessment of the computerised system.		211.68(b)[2]	820.30(g)		812.66[3] ICH Q9 Quality Risk Management. ICH Q7 5.40 ICH E6 (R2) 5.0.2 ICH E6 (R2) 1.65 NIST, Risk Management Guide for Information Technology Systems, Special Publication 800- 30. GHTF, Implementation of risk management principles and activities within a Quality Management System. ISO 14971:2007 , Medical devices -- Application of risk management to medical devices GAMP Forum, Risk Assessment for Use of Automated Systems Supporting Manufacturing Process -- Risk to Record, Pharmaceutical Engineering, Nov/Dec 2002. GAMP/ISPE, Risk Assessment for Use of Automated Systems Supporting Manufacturing Process --

[2] Federal Register, Vol 60 No. 13, 4087-4091, January 20, 1995.
[3] All 21 CFR Part 812 regulations apply equally to both paper records and electronic records. The use of computer systems in clinical investigations does not exempt IDEs from any Part 812 regulatory requirement.

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	References				
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					Functional Risk, Pharmaceutical Engineering, May/Jun 2003. EU Annex 20. US FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices, May 2005. Pressman, Roger S., Software Engineering – A Practitioner's Approach, McGraw Hill. GAMP 5 –Management Appendices M3 and M4; Operational Appendices O2, O6, O8, O9. ISO 13485 7.3.6 WHO, Technical Report Series No. 281, 2013. Health Canada API , C.02.05, Interpretation #12. Articles 3. 6, 12 draft Annex 2 CFDA GMP. OECD Guidance Document, Section 1.2. ANMAT (Argentina) 5.21 US FDA General Principles of Software Validation Section 4.8 PIC/S Guidance PI 011-3, Sections 4.5 and 4.6. Section 5.3 PIC/S PI 041-1 (Draft3).

	References				
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					Section 5.0, WHO, Technical Report Series No. 995, 2016. Sections 6.2 and 9.2 Russian Federation DI Guideline Sections 4.7 and 5 in WHO QAS19_819. CEFIC DI Best Practices Guide for API (FINAL March 2019) Guide to CSV, Anvisa Sections 4.1.4, 6.0 DI OECD, Sections 5.4 and 5.5 MHRA Section 5.3 EMA GCP 4.6
2. Personnel. There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Qualified Persons and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties. (Data quality element: Attributable)	11-1	211.101(d), 211.122, 211.186, 211.188(b)(11)	820.20(b)(1) and (2); 820.25	11.10(i) 11.10(j) 11.100(b)	EudraLex, The Rule Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practices for Medicinal Products for Human and Veterinary Use, Part 1, Chapter 2 – Personnel, February 2014 21 CFR 110(c). 21 CFR 606.160(b)(5)(v). 21 CFR Part 312.53(a) and .53(d). 21 CFR 58.29 WHO - Technical Report Series, No. 937, 2006. Annex 4, Section 13 GAMP 5 6.2.3.1, 6.2.3.3, 6.2.3.3. 6.2.3.5 and Operational Appendix

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					O12. ISO 13485 5.5; 5.5.1; 5.5.3; 6.2; 6.2.1; 6.2.2 Japan CSV Guideline (Guideline on Management of Computerized Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi-drugs, October 2010) , Section 6.8. Thailand CSV GMPs, Clause 510. Health Canada API, C.02.006 OECD Guidance Document, Section 1.3. Brazil API (RDC Resolution #69 Chapter VI Section VI Art. 258)) US FDA Data Integrity (Draft) Guidance III.16 Section 8.0, WHO, Technical Report Series No. 995, 2016. Section 6.4.3 Russian Federation DI Guideline DI NMPA (former CFDA) Article 10 EMA GCP 5.3
3. Suppliers and Service Providers. 3.1 When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a	11-18	Sub Part B 211.34	820.20(b)(1) and (2), 820.50		EudraLex, The Rules Governing Medicinal Products in the European Union Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary

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computerised system or related service or for data processing, formal agreements must exist between the manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party. IT-departments should be considered analogous. 3.2 The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment. 3.3 Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled. 3.4 Quality system and audit information relating to suppliers or developers of software and implemented systems should be made available to inspectors on request. (Data quality element: Available) 4.5 The supplier should be assessed appropriately.					Use, Chapter 7: Outsourced Activities, January 2013. 21 CFR 110(c). ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients ICH Q10 Section 2.7 Management of Outsourced Activities and Purchased Materials. WHO - Technical Report Series, No. 937, 2006. Annex 4. Appendix 5, Section 6.2. GAMP 5 Section 6.1.4. GAMP 5 –Management Appendices M2 and M6. ISO 13485 5.5; 5.5.1; 5.5.3; 6.2; 6.2.1; 6.2.2' 7.4; 7.4.1. China GMPs, Section 7. Thailand CSV GMPs, Clause 527. PDA, Technical Report No. 32 Auditing of Supplier Providing Computer Products and Services for Regulated Pharmaceutical Operations, PDA Journal of Pharmaceutical Science and Technology, Sep/Oct 2004, Release 2.0, Vol 58 No 5. CEFIC CSV Guide, Section 7.4.6.

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					Article 4 draft Annex 2 CFDA GMP. OECD Guidance Document, Section 1.6. PIC/S Guidance PI 011-3 Sections 5.1, 5.2, 11. Section 10.0, PIC/S PI 041-1 (Draft3). Section 7.0, WHO, Technical Report Series No. 995, 2016. Section 9.3 Russian Federation DI Guideline Section 7, WHO QAS19_819 Guide to CSV, Anvisa Section 4.1.5 DI NMPA (former CFDA) Article 11 MHRA Section 10 EMA GCP Annex 1, Section 5.1, Section 6.7
Project Phase.					OECD Guidance Document, Section 2
4. Validation. 4.1 The validation documentation and reports should cover the relevant steps of the life cycle. Manufacturers should be able to justify their standards, protocols, acceptance criteria, procedures and records based on their risk assessment. 4.2 Validation documentation should include change control records (if applicable) and reports on any deviations observed	11-2; 11-4; 11-5; 11-7	211.68; 211.100(a), (b).	820.3(z), 803.17 820.40 820.170 820.30(g), 820.70(g) 820.70(i). 820.70(i)	11.10(a); 11.10(k); 11.10(h); 11.300(e)	EU Directives 2017/1572, Article 9 Section 2. ISO 90003:2004, Sections 7.3.2; 7.3.3; 7.3.4; 7.3.5; 7.3.6.2a; 7.3.6.2.b; 7.3.6.2.c; 7.5.1.5; 7.5.1.6; 7.3.6.2d; 7.3.7; 7.5.3.2 ISO-27000, Sections 12.1, 12.2 Medicines and Healthcare products Regulatory Agency (MHRA) (UK).

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during the validation process. 4.3 An up-to-date listing of all relevant systems and their GMP functionality (inventory) should be available. For critical systems an up-to-date system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software pre-requisites, and security measures should be available. 4.4 User Requirements Specifications should describe the required functions of the computerised system and be based on documented risk assessment and GMP impact. User requirements should be traceable throughout the life cycle[4]. 4.5 The regulated user should take all reasonable steps, to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately. 4.6 For the validation of bespoke or customised computerised systems there should be a process in place that ensures the formal assessment and reporting of quality and performance measures for all the life-cycle stages of the system formal assessment and reporting of quality and performance measures			820.30(c); 820.3(z) and (aa); 820.30(f) and (g) 820.30 820.50		IEEE. PIC/S PI 011-3 Sections 6.3, 7, 9, 10, 13.2, 14.3, 23.8, 23.10 21 CFR 606.160(b)(5)(ii) and 606.100(b)(15). ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Sections 5.41, 12.2. ICH Q9 Quality Risk Management. 11-1 21 CFR 58.61; 63(a) and (c); 58.81(c) and (d); 58.33 21 CFR 59.190 Blood Establishment Computer System Validation in the User's Facility, April 2013. US FDA General Principles of Software Validation. WHO - Technical Report Series, No. 937, 2006. Annex 4. Appendix 5 GAMP 5 Sections 4.2.1, 4.2.3, 4.2.4, 5.2.3, 5.2.5, 6.1.5, 6.1.6, 6.2.6, 6.2.8,

[4] O. López, "*Requirements Management*", Journal of Validation Technology, Vol. 17 No. 2., Spring 2011.

	References				
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for all the life-cycle stages of the system. 4.7 Evidence of appropriate test methods[5] and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered[6]. Automated testing tools and test environments should have documented assessments for their adequacy. 4.8 If data are transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process[7]. (Data quality elements: Legible, Accurate, Complete, Consistent)					6.2.9, 6.2.10 GAMP 5 Development Appendices: D1 – D7; Management Appendices M1 – M10; Operational Appendix O1 21 CFR 1271.160(d) 21 CFR 803.17; 21 CFR 803.18 EU Annex 15. Brazilian Medical Devices (RDC No 16) Sections 1.2.4, 4.1.8, 4.2.1.1, 5.4.6, 5.5.2 and 5.5.3, 5.6. ISO 13485 2.3; 7.2; 7.2.1; 7.2.2; 7.5.1.2.2; 7.3.6; 6.3; 7.5.2. ISO/TR 14969:2004 7.5.2 ISO 27000 Section 7.1 Japan CSV Guideline (Guideline on Management of Computerized Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi- drugs, October 2010) , Sections 4, 5 and 9.

[5] Test methods -- With the Black-Box Test , the test cases are derived solely from the description of the test object, the inner structure of the object is thus not considered when creating the test plan; With the White-Box Test the test cases are derived solely from the structure of the test object; With the Source-Code Review the source code is checked against the documentation describing the system by one or several professionals. The APV Guideline ÓComputerized SystemsÓ based on Annex 11 of the EU-GMP Guideline, April 1996.
[6] This sentence is related with the additional checks covered in Accuracy Checks (11-6).
[7] Annex 11-4.8 is complemented with 11-7.1.

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					China GMPs Article 109. Thailand CSV GMPs, Clauses 511, 512, 513, 514, 516. Health Canada API , C.02.05 Interpretation #12; #13; #14; 17. C.02.015 Interpretation #3; #13.5 Articles 5, 7, 8, 9, 11, 13 drafts Annex 2 CFDA GMP. OECD Guidance Document, Sections 1.5., 1.7, 1.9, 2.1, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8 ANMAT (Argentina) 5.25 US FDA General Principles of Software Validation 4.1, 4.5, 5.1, 5.2, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.6, 23.10 Brazil API (RDC Resolution #69 Chapter VI Section VI) WHO Technical Report 986 Annex 2 (Section 15.9) ITIL Service Design (Section 5.2.8) US FDA Data Integrity (Draft) Guidance III.3 Part II - Basic Requirements for Active Substances used as Starting Materials, Section 5.41 and 5.42. Section 9.0, WHO, Technical Report Series No. 995, 2016.

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	References				
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					NSF 363-14 Section 6.3.2.3 (a) and (c) OMCL 7.3 Sections 8.2.4 and 9.2 Russian Federation DI Guideline Sections 9.4, 9.5, 9.6, and 9.7 Russian Federation DI Guideline Section 11, WHO QAS19_819. Section 9.2, PIC/S PI 041-1 (Draft3). Guide to CSV, Anvisa Sections 4.1.3, 5.0, 8.0, 9.0, 10.0, 12.0. DI OECD Sections 6.0, 7.10 DI NMPA (former CFDA) Chapter IV MHRA, Section 9.3 #2, #3, #4 MHRA Section 9.4 #1 EMA GCP Annex 2, Annex 5, Section 4.10, Section 6.1.2, Section 6.1.3, Section 6.9
Operational Phase.					GAMP 5 –Operational Appendix O12. OECD Guidance, Section 3. ANMAT (Argentina) 5.22 and 5.23 Part II - Basic Requirements for Active Substances used as Starting Materials, Section 5.44. Guide to CSV, Anvisa Section 11.0

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	References				
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5. Data. Computerised systems exchanging data electronically with other systems should include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks.[8] (Data quality elements: Accurate, Consistent)	11-6	211.68(b). 211.88. 211.194(d)	806.1 820.25 820.70(a) 820.180 820.184	11.10(a); 11.10(b); 11.10(e); 11.10(f); 11.10(g); 11.10(h); 11.30.	US FDA 425.400; 803.1; 803.10; 803.14; 806.10; 806.30; 58.15; 58.33; 58.35; 59.190 EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, Part I – Basic Requirements for Medicinal Products, Chapter 4 – Documentation. EU Directives 2017/1572, Chapter 9, Article 2. GAMP 5 –Operational Appendix O9. Thailand CSV GMPs, Clause 515. OECD Guidance, Section 2.9. ICH Q7 Section 5.45. ITIL, Service Design (Chapter 5.2.10) Section 9.2.1 (Data transfer between systems) and 9.5, PIC/S PI 041-1 (Draft). Section 12.13, WHO QAS19_819 PIC/S PI 041-1 (Draft3), Section 9.5-1. DI OECD Section 7.9

[8] Annex 11-5 is fundamental in erecs integrity and it is related with Annex 11-4.7.

	References				
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					DI NMPA (former CFDA) Article 26 item (2). MHRA Section 9.4 #1 EMA GCP Section 6.1.4
6. Accuracy Checks. For critical data[9] entered manually, there should be an additional check on the accuracy of the data. This check may be done by a second operator or by validated electronic means. The criticality and the potential consequences of erroneous or incorrectly entered data to a system should be covered by risk management.[10] (Data quality element: Accurate)	11-9	211.68(c).	820.25 820.70	11.10(f)	The APV Guideline "Computerized Systems" based on Annex 11 of the EU-GMP Guideline. EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, Part I - Basic Requirements for Medicinal Products, Chapter 4 – Documentation. PIC/S PI 011-3. EU Annex 11-1. WHO - Technical Report Series, No. 937, 2006. Annex 4. Appendix 5, Section 4.5. ISO 13485 6.2; 6.2.1; 6.2.2; 7.5. Thailand CSV GMPs, Clause 518. Health Canada API , C.02.015 Interpretation #18. Article 15 draft Annex 2 CFDA

[9] The term "critical data" in this context is interpreted as meaning data with high risk to product quality or patient safety. ISPE GAMP COP Annex 11 – Interpretation, July/August 2011.
[10] Annex 11-6 is another fundamental section related with erecs integrity.

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	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					GMP. OECD Guidance, Section 3.1. ANMAT (Argentina) 5.26 and 5.30 ITIL, Service Design (Chapter 5.2.10) Part II - Basic Requirements for Active Substances used as Starting Materials, Sections 5.45 and 5.49. OMC 7.3 Section 8.1.1 Russian Federation DI Guideline Section 9.4, WHO QAS19_819 PIC/S PI 041-1 (Draft3), Section 9.5-1. DI NMPA (former CFDA) Article 26 item (1). MHRA Section 9.7 EMA GCP Section 6.1.4
7. Data Storage. 7.1 Data should be secured by both physical and electronic means against damage. Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period. (Data quality elements: Legible, Complete, Enduring, Available)	11-13 11-14	211.68(b). 211.180(e).	803.1 820.20 820.40 820.180 806.1	11.10(c) 11.10(d) 11.10(e) 11.10(g) 11.10(h) 11.30.	812.38. EU Directives 2017/1572, Article 9 Section 2. PIC/S PI 011-3. EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, Part I - Basic Requirements for Medicinal Products, Chapter 4 –

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7.2 Regular back-ups of all relevant data should be done. Integrity and accuracy of back-up data and the ability to restore the data should be checked during validation and monitored periodically.[11] (Data quality elements: Legible, Accurate, Complete)					Documentation. ICH E6 GCP (2) 5.5.3(f). ICH Q7 5.48. 21 CFR 58.33; .190(d); .35; .195 Specific records retention requirements are found in applicable predicate rule. For example, 21 CFR 211.180(c), (d), 108.25(g), and 108.35(h), and 58.195. 812.140(a) and (b). WHO - Technical Report Series, No. 937, 2006. Annex 4. Appendix 5, Sections 5 and 7.2.2. 21 CFR 123.9(f) GAMP Appendix O9 and O11. ISO 13485 6.2; 6.2.1; 6.2.2; 7.5 Japan CSV Guideline (Guideline on Management of Computerized Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi-drugs, October 2010) , Section 6.3. Japan's Pharmaceutical and Food Safety Bureau "Using electromagnetic records and electronic signatures for application

[11] Annex 11-7 is another fundamental section related with erecs integrity.

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	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					for approval or licensing of drugs", Section 3, April 2005. Thailand CSV GMPs, Clause 517, 522, 523. Health Canada API , C.02.05, Interpretation #16. Article 19 draft Annex 2 CFDA GMP. OECD Guidance, Section 3.2, 3.11. GAMP 5, Section 4.3.6.1. ISO 27000, Section 10.5 Brasil API (RDC Resolution #69 Chapter VI Section VI Article 269) WHO Technical Report 986 Annex 2 (Section 15.9) ITIL, Service Design (Chapter 5.2.11) US FDA Data Integrity (Draft) Guidance III.1.e 211.68(b); 211.188; 211.194. Part II - Basic Requirements for Active Substances used as Starting Materials, Section 5.48. Section 9.7, PIC/S PI 041-1 (Draft3). OMLC 7.3 and 7.4 Sections 8.2.3 and 9.8.4 Russian

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					Federation DI Guideline Sections 12.23, 12.12.24, and 11.27, WHO QAS19_819 Health Canada GMP Guidelines 4-7. DI OECD Section 7.21 MHRA Section 9.9 #1, #3 EMA Section 6.8
8. Printouts. 8.1 It should be possible to obtain clear printed copies of electronically stored e-records. (Data quality element: Legible) 8.2 For records supporting batch release it should be possible to generate printouts indicating if any of the e-record has been changed since the original entry.[12] (Data quality element: Original)	11-12	211.180©. 211.194(a).	43 FR 31508, July 21, 1978 803.1 803.10 803.14 806.30 820.40 820.180 806.1	11.10(b)	812.150, 58.15 Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures. PIC/S PI 011-3. FDA, Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application, August 2003. The APV Guideline, "Computerized Systems" based on Annex 11 of the EU-GMP Guideline. US FDA CPG Sec. 130.400 Use of Microfiche and/or Microfilm for

[12] Annex 11-8 is another fundamental section related with erecs integrity.

	References				
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					Method of Records Retention. ISO 13485 4.2.3; 4.2.4. Thailand CSV GMPs, Clause 521. OECD Guidance Document, Section 3.3. MHRA Section 9.9 #4
9. Audit Trails Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed.[13] (Data quality elements: Legible, Original, Complete) ***Note:*** In addition to the system generated audit trail, some implementation included the documentation that allows reconstruction of the course of events. Implicitly, this approach does not require a computer system generated audit trail.	11-10	211.180©	803.18 820.40	11.10©; 11.10(k)(2); 11.50 (a)(2)	1978 US CGMP rev. Comment paragraph 186. FDA, Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 2003. The APV Guideline "Computerized Systems" based on Annex 11 of the EU-GMP Guideline. PIC/S PI 011-3. PIC/S PI 041-1 (Draft3), Section 9.4 ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. ICH E6 GCP (R2) 4.9.0, 5.5.3©, 5.5.4 21 CFR 58.130(d); 211.160(a);

[13] Annex 11-9 is another fundamental section related with erecs integrity.

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	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					211.194; 212.110(b) Glossary of the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). ISO 13485 4.2.3 Thailand CSV GMPs, Clause 519. Health Canada API , C.02.05, Interpretation #15. OECD Guidance Document, Section 3.4. WHO Technical Report 986 Annex 2 (Section 15.9) US FDA Data Integrity (Draft) Guidance III.1.c; 7 & 8. Part II – Basic Requirements for Active Substances used as Starting Materials, Section 5.43. EU Directives 2017/1572, Article 9 Section 2. Sections 8.3.1 and 8.3.2 Russian Federation DI Guideline Sections 12.14 – 12.17, WHO QAS19_819 PIC/S PI 041-1 (Draft3), Section 9.5-2. DI OECD Section 7.16 MHRA Section 9.6 EMA GCP Section 6.2

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	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
10. Change and Configuration Management Any changes to a computerized system including system configurations should only be made in a controlled manner in accordance with a defined procedure. (Data quality elements: Legible and Accurate)	11-11	211.68. 211.180©.	820.30(i). 820.70(i). 820.40.	11.10(d); 11.10©	ISO 90003, 2004, Sections 7.3.7 and 7.5.3.2 PIC/S PI 011-3. The APV Guideline "Computerized Systems" based on Annex 11 of the EU-GMP Guideline. WHO – Technical Report Series, No. 937, 2006. Annex 4. Section 12 Pressman, Roger S., *Software Engineering – A Practitioner's Approach*, McGraw Hill. GAMP 5 –Management Appendix M3; GAMP 5 –Operational Appendices O6 and O7. GAMP 5 Section 4.3.4.1. ISO 13485 7.3.7; 7.5.2; 4.2.3 Japan CSV Guideline (Guideline on Management of Computerized Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi-drugs, October 2010) , Section 6.6. China GMP, Articles 240 – 246. Thailand CSV GMPs, Clause 520. Health Canada API , C.02.015 Interpretation #20. Article 17 draft Annex 2 CFDA GMP.

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					OECD Guidance Document, Sections 1.8, 2.2, 3.5, 4. ANMAT (Argentina) 5.28. ICH E6 (R2) Section 5.5.4(h). ICH Q7 Section 5.47. General Principles of Software Validation Sections 4.7 and 5.2.7. Part II – Basic Requirements for Active Substances used as Starting Materials, Section 5.47. NSF 363-14 Section 6.3.2.3 © Section 9.8.3 Russian Federation DI Guideline
11. Periodic evaluation Computerised systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation records, incidents, problems, upgrade history, performance, reliability, **security** and validation status report(s). (Data quality element: Accurate)		211.68; 211.180©.	820.20©.	11.10(k); 11.300(b) and ©.	US FDA CPG 7132a.07, Computerized Drug Processing; Input/output Checking. ICH Q7, 12.60 WHO – Technical Report Series, No. 937, 2006. Annex 4. Appendix 5, Section 1.5 GAMP 5 Section 4.3.5. GAMP 5 –Management Appendix M3; GAMP 5 –Operational Appendices O3 and O8 58.35; 58.190; 58.195. Annex 15 clauses 23 and 45. ISO 13485 5.6; 5.6.1; 5.6.2; 5.6.3; 8.2.2; 8.5; 8.5.1.

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					China GMPs Section 8. OECD Guidance Document, Section 3.6. ITIL, Service Design (Chapter 5.2.13) Section 9.8.8 Russian Federation DI Guideline Section 4.6 in WHO QAS19_819. MHRA, Sections 9.3 #5 and 9.8
12. Security 12.1 Physical and/or logical controls should be in place to restrict access to computerized system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas. (Data quality element: Attributable) 12.2 The extent of security controls depends on the criticality of the computerized system. 12.3 Creation, change, and cancellation of access authorisations should be recorded. 12.4 Management systems for data and for documents should	11-8	211.68(b) 211.160(a)		11.10(b); 11.10©; 11.10(d); 11.10(g); 11.300.	PIC/S PI 011-3, Sections 19.2; 19.3. PIC/S PI 041-1 (Draft3), Section 9.3. ICH E6 GCP (R2) 5.5.3 (d), © ICH Q7 Section 5.43. 21 CFR Part 58.51 ; 58.190(d) ; 211.68(b) WHO – Technical Report Series, No. 937, 2006. Annex 4. Appendix 5 Section 4 GAMP 5, Section 4.3.7.1 GAMP 5 –Management Appendix M9; GAMP 5 –Operational Appendix O11. Japan CSV Guideline (Guideline on Management of Computerized

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
be designed to record the identity of operators entering, changing, confirming or deleting data including date and time.[14] (Data quality elements: Attributable, Contemporaneous)					Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi-drugs, October 2010) , Section 6.4. Thailand CSV GMPs, Clause 517. Health Canada API , C.02.05, Interpretation #15. Articles 14, 16 draft Annex 2 CFDA GMP. OECD Guidance Document, Section 3.7. ANMAT (Argentina) 5.24. ISO-27000, Sections 12.1 and 11.2. WHO Technical Report 986 Annex 2 (Section 15.9) ITIL, Service Design (Chapter 5.2.13) EU Directives 2017/1572, Article 9 Section 2. US FDA Data Integrity (Draft) Guidance III.4 & .5. Part II – Basic Requirements for Active Substances used as Starting Materials, Section 5.43. NSF 363-14 Section 6.3.2.3 (b)

[14] Annex 11-12 is another fundamental section related with erecs integrity.

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					OMCL Section 7.1 Sections 8.2 and 9.8.1 Russian Federation DI Guideline Sections 12.7- 12.10, WHO QAS19_819 MHRA Section 9.5 EMA GCP Annex 3, Annex 4, Section 5.4
13. Incident Management. All incidents, not only system failures and data errors, should be reported and assessed. The root cause of a critical incident should be identified and should form the basis of corrective and preventive actions.	11-17	211.100(b)	820.100		ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Section 5.46. ICH E6, Section 5.1.3. GAMP 5 – Operational Appendices O4. O5,and O7. ISO 13485 8.5; 8.5.1; 8.5.2; 8.5.3 Japan CSV Guideline (Guideline on Management of Computerized Systems for Marketing Authorization Holder and Manufacturing of Drugs and Quasi-drugs, October 2010) , Sections 6.7 and 7.2. China GMPs, Sections 5 and 6. Thailand CSV GMPs, Clause 526. Health Canada API , C.02.015 Interpretation #19. Articles 20 and 21 draft Annex 2 CFDA GMP. OECD Guidance Document,

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					Section 3.8. ANMAT (Argentina) 5.27. US FDA General Principles of Software Validation, Section 5.2.7. Part II – Basic Requirements for Active Substances used as Starting Materials, Section 5.46.
14. Electronic Signature. Electronic records may be signed electronically. Electronic signatures are expected to: • have the same impact as hand-written signatures within • the boundaries of the company[15], • be permanently linked to their respective record, • include the time and date that they were applied. (Data quality element: Contemporaneous)				11.3(b)(7); 11.10©; 11.50; .70, .100, .200, .300	EU GMP Chapter 4 Principle Annex 11-8.1, 9, 12.4, 17 ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Section 5.43. Electronic Signatures in Global and National Commerce (E-Sign), a US federal law. (available at: http://thomas.loc.gov/cgi-bin/query/z?c106:S.761:) 21 CFR 58.33; .81; .35; .120; .185 Japan's Pharmaceutical and Food Safety Bureau "Using electromagnetic records and electronic signatures for application

[15] The phase "within the boundaries of the company" clarifies that such signatures applied to records maintained by the regulated company are not subject to Directive 1999/93/EC on a Company framework for esigs, nor the 2000/31/EC Directive on electronic commerce, nor any associated national regulations of EU member states on such topics.

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					for approval or licensing of drugs", Section 4, April 2005. Article 22 draft Annex 2 CFDA GMP. Guidance Document, Section 3.10. US FDA Data Integrity (Draft) Guidance III.11. Sections 12.18 – 12.19, WHO QAS19_819 DI OECD Section 7.17 MHRA Section 9.5 #4 EMA GCP 4.8
15. Batch release. When a computerized system is used for recording certification and batch release, the system should allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batches. This should be performed using an electronic signature. (Data quality element: Attributable)	11-19	211.68 211.186 211.192 211.188(b) (11) 211.188(a)		11.70; Sub Part C	21 CFR 211.68 The APV Guideline "Computerized Systems" based on Annex 11 of the EU-GMP Guideline. 11-9; 11-14 EC Directive 2001/83. Thailand CSV GMPs, Clause 528. Article 21 draft Annex 2 CFDA GMP.
16. Business Continuity. For the availability of computerized systems supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system breakdown (e.g., a manual or alternative system). The time required to bring the alternative arrangements into use should be based on risk	11-15 11-16				PIC/S PI 011-3. GAMP 5, Sections 4.3.6.2 and 4.3.6.3. GAMP 5 –Operational Appendix O10. Thailand CSV GMPs, Clause 524, 525.

	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
and appropriate for a particular system and the business process it supports. These arrangements should be adequately documented and tested.[16] (Data quality element: Available)					OECD Guidance Document, Section 3.12. ANMAT (Argentina) 5.29. ICH Q7, Section 5.48. NSF 363-14 Section 6.3.2.3 (d) 2001/83, Article 81. Section 9.6.6 Russian Federation DI Guideline
17. Archiving. Data may be archived. This data should be checked for accessibility, readability and integrity. If relevant changes are to be made to the system (0e.g., computer equipment or programs), then the ability to retrieve the data should be ensured and tested. (Data integrity elements: Legible, Enduring, Available)		211.68(b). 211.180©.		11.10©	Scientific Archivists Group, A Guide to Archiving of Electronic Records, 2014 www.sagroup.org.uk/images/documents/AGuidetoArchivingElectronicRecordsv1.pdf DOD 5015.2-STD, Design Criteria Standard for E-records Management Software Applications. GAMP 5 –Operational Appendix O13. GAMP GPG: Electronic Data Archiving, 2007. Draft OECD Guidance Document, Section 3.12. Scientific Archivists Group, "A Guide to Archiving of Electronic

Field Code Changed

[16] Annex 11-16 is another fundamental section related with erecs integrity.

Crosswalk between EU Annex 11 and
US FDA – 211, 820, 11; other guidelines and regulations
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	References				
	Old Annex 11	**211**	**820**	**11**	**Others/Guidelines**
					Records" ITIL, Service Design (Chapter 5.2.13) EU Directives 2017/1572, Article 9 Section 2. OMCL Section 6.9 and 7.4 Section 8.4.2and 9.8.7 Russia Federation DI Guideline. Section 9.7, PIC/S PI 041-1 (Draft3) DI OECD Section 7.22. MHRA Sections 9.4 #3, 9.9 #2 and #4 EMA GCP 6.10

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Revision History

Date	Update Reason
02-FEB-2011	Creation of the Annex 11 matrix.
21-FEB-2011	Updated format of matrix and updated based on various references.
08-MAR-2011	Updated various 21 CFR 820 references based on the US FDA General Principles of Software Validation, January 2002, CDRH and CBER.
13-MAR-2011	Updated various 21 CFR 211 references based on the US FDA Guide to Inspection of Computerized Systems in Drug Processing, February 1983.
22-MAR-2011	Updated various 21 CFR 11 references based on regulation. Add raw data references. Updated periodic review based on comments by Jeffrey Torres.
31-MAR-2011	Updated "Principle" reference based on US FDA CPG 7348.810 - Sponsors, CROs, and Monitors. Updated various 21 CFR 820 references based on another matrix correlating various regulatory requirements. Updated various references based on ICH E6 GCP, 21 CFR 58, and 21 CFR 312.
09-APR-2011	Added ISO 14971 as a reference. Updated 11-7 based on 21 CFR 820.
23-APR-2011	Updated various references based on various CFRs.
11-MAY-2011	Updated based on regulations for Computerized Systems Used in Medical Device Clinical Investigations, 21 CFR 812.
12-JUN-2011	Added 211.194(d) in Data Section; Added reference on my recent article on Requirements Management, published by IVT; Section 4, added the Blood Establishment Computer System Validation in the User's Facility, October 2007 (Draft Guidance); added as a reference EMA/INS/GCP/454280/2010 GCP Inspectors Working Group (GCP IWG), "*Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials*."; Updated various references based on 21 CFR 58.
03-AUG-2011	Added regulatory requirements about 820 based on the US FDA Medical Devices QS Manual: A small entity compliance guide, Chapter 7; added in periodic review reference of ICH Q7, 12.6; Modifications to Old-New Annex 11 mappings.
23-AUG-2011	Added WHO Technical Report Series, No. 937, 2006. Annex 4. Appendix 5. 2006
26-AUG-2011	Added Electronic Signatures in Global and National Commerce (E-Sign), a US federal law
25-SEP-2011	Added GAMP 5 Cross references (Yves Samson); added definition of Test Methods based APV guideline.
24-OCT-11	Added Tissues Reg 21 CFR 1271.160(d); Food 21 CFR 123.9(f)
17-MAR-2012	Updated based on NEMA Presentation. "Part 11 Recommendations for Changes", June 2004.
21-OCT-12	Updated based on presentation FDA Public Meeting June 2004 (R. Eaton and R. Nabar)

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Date	Update Reason
15-NOV-2012	Updated various references-based ICH Q10, ISPE GAMP COP Annex 11 – Interpretation, July/August 2011.
2-DEC-12	Updated based on Brazilian GMPs, Title VII Resolution of the Executive Board No. 17, Computerized Information Systems. This can be found on page 109 de 148, http://www.in.gov.br/imprensa/visualiza/index.jsp?jornal=1&pagina=94&data=19/04/2010
07-APR-13	Updated guideline Blood Establishment Computer System Validation in the User's Facility, from October 2007 (Draft Guidance) to April 2013 (Final Guidance).
24-AUG-13	Updated with ISO 134854.
24-Oct-13	Added Japanese CSV Guidelines (Guidelines on Management of Computerized Systems for Marketing Authorization Holders and Manufacturers of Drugs and Quasi-drugs, October 2010) and Japan's Pharmaceutical and Food Safety Bureau "Using electromagnetic records and electronic signatures for application for approval or licensing of drugs", April 2005.
31-Oct-13	Added State Food and Drug Administration, P.R. China, March 2011 and Thailand CSV GMPs contained in the Prescription of Details regarding and Procedures of Manufacture of Modern Medicinal Products in compliance with Drug Lawa B.E.2554.
08-Feb-14	Added 91/412/EEC; WHO, Technical Report Series No. 981 PDA, Technical Report No. 32; CEFIC CSV Guide Rev 2, December 2002. Health Canada GMP Guidelines for API (GUI-0104) Dec 2013.
08-Feb-14b	Corrected copy. Added couple of sections left out from the Health Canada GMP Guidelines for API.
26-Mar-14	Updated application sections based on ICH E6 GCP.
09-Jul-14	Incorrect references in 21 CFR Part 58, Security. China Food & Drug Administration (CFDA) draft of GMP Annex 2 Computerized Systems.
12-Sep-14	Added reference GAMP GPG: Electronic Data Archiving, 2007 to Archiving; Added reference GAMP GPG: IT Infrastructure Control and Compliance, 2005 to Principle b. Added reference ISO/TR 14969:2004 Medical devices -- Quality management systems -- Guidance on the application of ISO 13485. Added EudraLex, The Rules Governing Medicinal Products in the European Union Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Chapter 7: Outsourced Activities, January 2013 to Suppliers and Service Providers.
23-Sep-14	Added Draft OECD Guidance Document – The Application of GLP Principles to Computerised Systems, September 2014. (Note: The entries related with this DRAFT, were replaced with the final document. Refer 21Feb18 entry.)
10-Oct-14	Based on the definition by the NIST (SP 800-33), highlighted the data integrity related items on Annex 11.
19-Dec-14	Added ISO 90003:2014 applicable sections related with Configuration Management and applicable development phase activities.
05-Mar-15	Added ICH E6, Guideline for GCP (Jun 1996). Added Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medicas (ANMAT) (Argentina's Ministerio de Salud Presidencia de la Nacion). Added ISO/IEC 27000 Information Security Management Systems. Added US FDA General Principles of Software Validation. Fixed minor errors.

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Date	Update Reason
01-Aug-15	In 11-17 added Scientific Archivists Group, "A Guide to Archiving of Electronic Records", as a reference. Added Brazil API Regulations (RDC Resolution #69)
14-Nov-15	Added WHO Guide regarding the Principles of GMP Technical Report 986, Annex 2 WHO good manufacturing practices for pharmaceutical products: main principles. Added ITIL Service Design, Chapter 5.2 – Management of data and information, 2011 Edition
22-Apr-16	Added US FDA Guidance for Industry: Data Integrity and Compliance with CGMP (Draft)
11-Aug-16	Added Part II - Basic Requirements for Active Substances used as Starting Materials Added EMA Q&A: GMP Data Integrity, August 2016. Added MHRA GxP Data Integrity Definitions and Guidance for Industry, July 2016 (Draft) Added PIC/S, Good Practices for Data Management and Integrity in Regulated GMP/GCP Environments," PI 041-1 (Draft2), August 2016. TGA intends to reference the PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments, PI 041-1 (Draft 2) Added WHO Guidance on Good Data and Record Management Practices, Technical Report 966, Annex 5 WHO Expert Committee on Specifications for Pharmaceutical Preparations.
28-Sep-16	Added NSF/IPEC/ANSI 363 – 2014 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients
24-Sep-17	ICH E6 (R2) GCP Guideline (2016); Updated articles in EU GMP Directive 2003/94/EC with applicable articles in the new Directive 2017/1572; OMCL Management of Documents and Records (January 2016).
04-Nov-17	Integration of Q13 in Added EMA Q&A: GMP Data Integrity, August 2016 with Added US FDA Guidance for Industry: Data Integrity and Compliance with CGMP (Draft).
21-Feb-18	Replaced "Data integrity element" with "Data quality element:"; Replaced Draft OECD Guidance Document – The Application of GLP Principles to Computerised Systems, September 2014 with the final version April 2016.
04-Apr-18	The entries related with MHRA GxP Data Integrity Definitions and Guidance for Industry; July 2016 (Draft) were replaced with the final document. Refer 11Aug16 entry. The final guidance document, MHRA GxP Data Integrity Guidance and Definitions was published on March 2018.
26-May-19	Updated entries with Russia Federal State Institute of Drugs and Good Practices (Draft) https://drive.google.com/file/d/1lMdc7QQkz6h_tinHpJBvb-WMby6WNe4C/view?usp=sharing
03-Nov-19	Entries updated based on WHO QAS19_819_data_integrity (Draft October 2019) and CEFIC Data Integrity Best Practices Guide for API (FINAL March 2019). Updated PIC/S PI Draft 2 references with PIC/S 041_1 Draft_3_Guidance on Data Integrity.
23-Feb-20	Updated based on Health Canada, Good Manufacturing Practices (GMP) Guidelines - 2018 Edition, Version 3 (GUI-0001). Updated using data integrity elements only in Canadian Guideline.
30-Mar-20	Correlated 211.68(a) and EU Annex-11 Principle 1.
29-Jul-20	Updated based on Guide to CSV, Anvisa (April 2020)

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Date	Update Reason
09-Sep-20	OECD_Advisory_Document_on_GLP_Data_Integrity (Draft 20200807); NMPA (former CFDA), Data Record and Management (December 2020)
02-Jul-21	MHRA PI 041-1, Good Practice for Data Management and Integrity in Regulated GMP-GDP Environments, Jul 2021; EMA, Guideline Computerized Systems Electronic Data Clinical Trials (Draft 10Jun2021)