**北京沃丰时代数据科技有限公司**

**Beijing Wofeng Times Data Technology Co. Ltd.**

**文档与记录管理规定**

**Documentation and Records Management Requirements**

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**Document Information：**

|  |  |  |  |
| --- | --- | --- | --- |
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1. 总则

Chapter I General

* + 1. 为规范北京沃丰时代数据科技有限公司（以下简称“沃丰时代”或“公司”）文档管理要求，提高文档管理能力，特制定本规定。

Article 1 In order to standardize the document management requirements of Beijing Wofeng Times Data Technology Co., Ltd (hereinafter referred to as "Wofeng Times" or "Company ") and improve the procedure of document management, this regulation is formulated.

* + 1. 本规定适用于公司的文档管理工作。

Article 2 This regulation applies to the all the documents in all the business processes within the company.

1. 释义和分类

Chapter II Interpretation and classification

* + 1. 文档是指以文字或图示描述管理内容或业务内容、通过规定程序由有权人员签署发布、要求接收者据此做出规范反应的电子文档或纸质文档。

Article 3 A document is an electronic document or paper document that describes the management or business content in words or diagrams, is signed and published by the authorized person through a prescribed procedure, and requires the receiver to make a normative response accordingly.

第一款：软件生命周期内的GxP相关的产品和验证文档在起草、审核、和批准的过程中遵循相应的审批矩阵，具体信息见审批矩阵表格。

Section1: the GxP related products and validation documents within the software lifecycle phases should follow the corresponding approval matrix in the process of document drafting, review, and approval. Refer to the approval matrix for detailed information as below:

表1：GxP流程和验证交付物审批矩阵

Table 1: GxP Procedures and Validation Deliverables Approval Matrix

|  |  |  |  |
| --- | --- | --- | --- |
| 交付物  Deliverables | 作者  Responsible | 审核人  Reviewers | 批准人  Approvers |
| 验证计划(VP)  Validation Plan(VP) | 开发工程师  Developer | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 用户需求说明(URS)  User Requirements Specification(URS) | 开发工程师  Developer | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 风险分析(RA)  Risk Assessment (RA) | 开发工程师, 测试工程师  Developer, Tester | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 功能说明(FS)  Functional Specifications (FS) | 开发工程师  Developer | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官  CTO |
| 设计说明(DS)  Design Specifications (DS) | 开发工程师  Developer | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官  CTO |
| 配置说明(CS)  Configuration Specifications (CS) | 开发工程师  Developer | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官  CTO |
| 测试计划  Test Plan | 测试工程师  Tester | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 测试报告  Test Report | 测试工程师  Tester | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 追溯矩阵(TRM)  Traceability Matrix (TRM) | 开发工程师, 测试工程师  Developer, Tester | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |
| 验证报告(VR)  Validation Plan(VR) | 开发工程师, 测试工程师  Developer, Tester | 研发经理, 研发总监  R&D Manager,  R&D Director | 首席技术官，质量保证部  CTO, QA |

第二款：GxP相关文件将在签署后发布，任何人不得对其进行修改。如需修改，则需要批准和签名过程，并在之后公布。

Section 2: GxP the relevant documents will be published after signing, once approved the documents shall not be amended by anyone. For modification, approval and signature process is required and published afterward.

* + 1. 记录是由公司运营中所产生的，证明公司运营的各类证据。

Article 4 The records are generated by the operation of the company and prove all kinds of evidence of the operation of the company.

1. 职责分工

Chapter III Division of duties

* + 1. 各部门负责：

1. 确定文档密级；
2. 管理本部门文档登记、保管、销毁；
3. 控制文档版本，保证文档版本为最新版本；

Article 5 Related departments are responsible for:

1. Determine document classification;
2. To manage the registration, storage and destruction of the departments’ documents;
3. Control the document version to ensure that the document version is the latest version.
4. 文档密级

Chapter IV Document Confidentiality Classification

* + 1. 应根据文档的机密性进行密级划分，文档密级划分参见《信息资产安全管理制度》的信息资产分级相关要求、《数据分类分级标准规范》数据安全分级相关要求。

Article 6 The documents should be classified based on According to the confidentiality. The classification of documents is set up in the related requirements of information asset classification defined in "Information Asset Security Management System", and in the related requirements of data security classification defined in “Data Classification Standard Specification”.

* + 1. 电子文档和纸质文档需要依据机密性级别进行相应安全控制，具体内容如下：

Article 7 Electronic and paper documents need to be controlled according to the level of confidentiality, as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **信息处理方式**  **Information processing modalities** | **机密（4级）**  **Confidential (Level 4)** | **秘密（3级）**  **Secret**  **(Level 3)** | **内部（2级） Internal (level 2)** | **公开（√级） Disclosure (√ level)** |
| 标识  Identification | 在文件封面及内页均应标注  The cover and inner pages should be marked | 在文件封面及内页均应标注  The cover and inner pages should be marked | 在文件封面及内页均应标注  The cover and inner pages should be marked | 无要求  No requirement |
| 授权  Authorization | 应得到文档所有者授权  Should be authorized by the document owner | 应得到文档所有者授权Should be authorized by the document owner | 应得到文档所有者授权Should be authorized by the document owner | 无要求  No requirement |
| 访问  Visits | 仅允许文档所有者和被文档所有者授权的极少数人员访问，访问此类信息资产应进行授权  Only document owners and very few people authorized by document owners are allowed access to such information assets should be authorized | 在信息公开范围内的使用者均可访问，其它人员一律不可访问  Access is available to users within the scope of information disclosure and not available to others | 公司员工可以访问，限制第三方人员访问  Access by company employees is restricted to third parties | 无要求  No requirement |
| 存储  Storage | 电子文档需加密存储在安全的计算机系统内；硬件介质与纸质文档需锁在安全的保险柜内；禁止以其他形式存储或展示  Electronic documents need to be encrypted and stored in a secure computer system; hardware media and paper documents need to be locked in a secure safe; other forms of storage or display are prohibited | 电子文档需妥善保存在设有安全控制的计算机系统内（建议进行信息加密）；  硬件介质应该妥善保管，严禁摆放在桌面；  硬件介质和纸质文档应该锁在安全的保险柜内  Electronic documents should be kept properly in a computer system with security controls (information encryption is recommended);  Hardware media should be properly kept, strictly prohibited placed on the desktop;  Hardware media and paper documents should be locked in a secure safe | 以恰当方式保存，避免被非授权人员获得；  存储有信息的移动介质应加密  (b) To preserve them in an appropriate manner and avoid being acquired by unauthorized persons;  Mobile media containing information should be encrypted | 无要求  No requirement |
| 复制  Copy | 应经文档所有者批准，并让专人操作或监督实施；  仅限公司范围内复制  Should be approved by the document owner, and let a person to operate or supervise the implementation;  Reproduction within company only | 得到文档所有者批准后方可复制且需要登记；  仅限公司范围内复制  Document owner approval before copying and need to register;  Reproduction within company only | 根据工作需要进行复制  Reproduction as required | 无限制  Unlimited |
| 打印  Print | 得到文档所有者批准后方可打印，打印时应有人值守；  Document owner approval before printing, printing should be manned;  仅限公司范围内打印；  打印件需要标注密级；  打印件应标注水印  Print only within company scope;  Print needs to be marked with a secret level;  Print should be marked with watermark | 得到文档所有者批准后方可打印，打印时应有人值守；打印件需要标注密级；  仅限公司范围内打印；  打印件应标注水印  Document owner approval before printing, printing should be on duty; printing need to be marked secret level;  Print only within company scope;  Print should be marked with watermark | 打印件需要标注密级  Print needs to be labeled secret | 无限制Unlimited |
| 邮件  Email | 禁止邮件直接发送，应在获得授权后经过电子签名和加密处理才可邮件发送  Direct mail delivery is prohibited and should be authorized by electronic signature and encryption before sending | 应经文档所有者许可，邮件需经过电子签名和加密处理才可邮件发送  Mail must be electronically signed and encrypted with the permission of the document owner | 为工作必须或经过授权  外发需加密附件。  Required or authorized for work  Outgoing need to encrypt attachment. | 无限制  Unlimited |
| 传真  Fax | 禁止传真  No Fax | 应经文档所有者批准后专人负责传真  With the approval of the document owner | 为工作必须或经过授权  Required or authorized for work | 无限制  Unlimited |
| 快递  Express delivery | 经授权后采取妥善的保护措施，由签署了特定安全协议的特定快递公司或专人快递  To take appropriate protective measures upon authorization by a specific courier company or person who has signed a specific security agreement | 经授权后，由签署了特定安全协议的特定快递公司快递  Upon authorization, express by a specific courier company that has signed a specific security agreement | 为工作必须或经过授权  Required or authorized for work | 无限制  Unlimited |
| 内部分发  Internal distribution | 经文档所有者批准后，密封分发，或以允许的电子分发形式进行安全的分发  Sealed distribution, with the approval of the document owner, or secure distribution in the form of permitted electronic distribution | 经文档所有者批准后，密封分发，或以允许的电子分发形式进行安全的分发  Sealed distribution, with the approval of the document owner, or secure distribution in the form of permitted electronic distribution | 无限制  Unlimited | 无限制  Unlimited |
| 对外分发  External distribution | 经文档所有者批准后分发，接收方需要签署特定得保密协议并进行登记  For distribution with the approval of the document owner, the recipient is required to sign and register a specific confidentiality agreement | 经文档所有者批准后分发，接收方需要签署特定得保密协议并进行登记  For distribution with the approval of the document owner, the recipient is required to sign and register a specific confidentiality agreement | 经授权后，以允许的分发方式分发  Distribution by authorized distribution | 无限制  Unlimited |
| 备份与恢复  Backup and recovery | 对于备份数据的安全控制措施不低于源数据安全等级  Security control measures for backup data are not lower than source data security level | 对于备份数据的安全控制措施不低于源数据安全等级Security control measures for backup data are not lower than source data security level | 确保数据可用  Ensure data availability | 无要求  No requirement |
| 处置  Disposal | 纸质文档应采用碎纸机销毁；定期检查电子文档敏感周期并及时消除；应彻底删除存储介质中的敏感信息；并检查确认上述处置  Paper documents should be destroyed by shred shredder; the sensitive period of electronic document should be checked regularly and eliminated in time; the sensitive information in the storage medium should be removed completely; and the above disposal should be checked and confirmed | 纸质文档应采用碎纸机销毁；定期检查电子文档敏感周期并及时消除；相关存储介质应彻底销毁；并检查确认上述处置  Paper documents should be destroyed by shredder; electronic documents should be regularly checked for sensitive periods and eliminated in a timely manner; relevant storage media should be completely destroyed; and the above disposal should be checked and confirmed | 纸质文档应采用碎纸机销毁；定期检查电子文档敏感周期并及时消除；相关存储介质内数据应清除  Paper documents should be destroyed by shredder; electronic documents should be checked regularly and eliminated in time; data in relevant storage media should be removed | 无要求  No requirement |
| 记录跟踪  Record tracking | 对文件复制、保存、浏览、销毁过程应有日志记录；应对这些记录实施严格的访问控制，稽核审计人员应该对这些记录进行定期的审计  Document reproduction, preservation, browsing and destruction should be documented; strict access control should be exercised and auditors should conduct regular audits of these records | 对文件复制、保存、浏览、销毁过程应有日志记录；应对这些记录实施严格的访问控制，稽核审计人员应该对这些记录进行定期的审计  Document reproduction, preservation, browsing and destruction should be documented; strict access control should be exercised and auditors should conduct regular audits of these records | 不建议跟踪  No recommended tracking | 不建议跟踪  No recommended tracking |

1. 电子数据保存规定

Chapter V Electronic Data Retention

* + 1. 电子数据保存的范围是全部电子数据都会保存（包含如数据库记录、文件、录音等）。

Article 8 The scope, type, and content of electronic data that will be stored and retained by Wofeng Times are all the electronic data (incl. Database records, documents, audio recording, etc).

* + 1. 电子数据的保存时限依据与客户合同的内容来具体定义， 一般合同定义为3年至5年，则电子数据保存3至5年(具体以合同定义的时限为准)，如果与客户的合同定义为永久保存，则电子数据的时限是永久保存。

Article 9 The data retention time will be defined by the detailed value in the requirements of signed contract. Normally it is set as three to five years in the signed contract with customer, the electronic data will be retained to three to five years following the contract; if it is required as permanent retention in the signed contract with customer, then the electronic data will be permanently retained.

* + 1. 对于J&J的ERS，应遵循相关要求、相关数据记录和操作记录，在产品/系统的生命周期内予以保存。

Article 10 For J&J ERS, follow the relevant requirements, relevant data records and operation records to be retained for life of the product/system.

1. 文档保管

Chapter VI Document Retention

* + 1. 各部门应指定专人进行相关的文档保管，并满足文档保管的基本需求。

Article 11 Each department shall appoint a special person to keep the relevant documents and meet the basic requirements of document keeping.

* + 1. 应根据文档密级，存储介质等因素，分类选择合适的地点进行文档的保管。

Article 12 According to the document level, storage media and other factors, the appropriate location should be selected for custody.

* + 1. 纸质文档在考虑到安全的基础之上，重点考虑防潮、防火等因素，磁介质文档保管级别应高于纸质文档保管级别，要充分考虑到防磁等因素，另外对于磁介质文档，还要考虑到恢复磁介质文档的应用环境。

Article 13 On the basis of considering safety, paper documents focus on moisture-proof, fire-proof and other factors. The storage level of magnetic medium documents should be higher than that of paper documents.

* + 1. 文档保存至系统退役后五年。文档包括软件要求的系统文档、规格或验证交付物、测试记录、系统中存储的投诉记录以及对公司产生重大影响的事件或操作记录，应保存超过五年，并在UIC系统里同步相应的数据存储时限。

Article 14 The documents are kept for five years after system retirement. Following documents should be retained the life of the product/system: system documentation that defines the software requirements, specifications or verification deliverables, test records, complaint records stored in the system, and also the high impacted events or operations records, and they shall be kept for more than five years and the corresponding data storage time limit shall be synchronized in the UIC system.

* + 1. 对于部门特殊的文档，原则上保管期限只能长于公司规定的最低期限。

Article 15 For department-specific documents, in principle, the period of custody can only be longer than the minimum period stipulated by the company.

* + 1. 在合同期结束后，对GXP相关的测试用例至少需要保存一个月以上。

Article 16 After the end of the contract period, GXP relevant test cases need to be saved for at least one month.

1. 文档更新

Chapter VII Document Update

* + 1. 当文档适用性无法满足使用要求，应作相应的更新。

Article 17 When the document applicability can not meet the use requirements, it should be updated accordingly.

* + 1. 文档更新应在此文档最新版本的基础上进行。

Article 18 document update should be based on the latest version of this document.

* + 1. 文档更新应遵循原有文档的编写要求，需要特别注意以下方面：

1. 填写文档中修改内容；
2. 填写文档中的修改人；
3. 填写文档版本号和修改时间；
4. 修改文档页眉、页脚。

Article 19 Document updates should follow the requirements of the original document special attention should be paid to:

1. Fill in the changes in the document;
2. Fill in the document with the modifier;
3. Fill in document version number and revision time;
4. Modify document header, footer.
   * 1. 文档版本命名规则如下：
5. 格式：V✕✕✕.✕✕✕；
6. 初始版本号为V0.1，最大版本号为：V999.999.；
7. 草稿状态的版本均为V0.✕✕✕，例如：V0.1，V02；
8. 经过评审通过的文档版本均为V1.0开始。

Article 20 The document version naming rules are as follows:

1. Format: V✕✕✕. ✕✕✕;
2. The initial version number V0.1, the maximum version number is: V999.999.
3. The version of the draft status is V0.✕✕✕, for example: V0.1,V0.2.
4. All approved document versions are V1.0.
   * 1. 如根据需要，需对已经过评审通过的文档进行更改，无论是修订还是迭代，均需重新进行审核评审，且文档版本号及历史记录页均需要相应更改记录，具体更改方法如下：
5. 草稿状态的版本均为V0.✕✕✕，例如：V0.1, V0.2，如需对此文件进行更改，版本号需进行自然迭代，且在历史记录页进行更改记录，如：V0.1改为V0.2；
6. 经过评审通过的文档版本均为V1.0开始，如需对此文件进行更改，版本号需进行自然迭代，且在历史记录页进行更改记录，如：V1.0改为V1.1； V1.1改为V2.0。

Article 21 If you need to change the approved document, whether it is a revision or iteration, you need to re-evaluate the document, and the document version number and history page need to be updated accordingly, the specific change method is as below:

1. The versions of the draft status are all V0.✕✕✕, e.g. V0.1,V0.2, changes to the document are required, the version number is naturally overridden and the changes are recorded on the history page, e.g. V0.1 to V0.2;.
2. The approved version of the document is V1.0. If you need to change the document, the version number is automatically overridden and the change record is made on the history page, e.g. V1.0 changed to V1.1; V1.1 to V2.0.
   * 1. 如果更新文档人员不是原文档编制人，则在更新后，应征得原文档编制人同意。如果原文档编制人已经不负责此文档的编制工作，应把编制人更新为当前更新文档人员。

Article 22 If the one updating document is not the author of the original document, after the update, the author of the original document should agree. If the original author is no longer responsible for the preparation of this document, the author should be updated and changed to the current person, who is actually updating the document.

* + 1. 文档更新时应通知与之内容相关联文档的编制人进行同步更新。

Article 23 Document updates should be notified to the author of the document associated with update the document synchronously.

* + 1. 文档更新应作好历史文档的备份。

Article 24 Document updates should be backed up with historical documents.

1. 附则

Chapter VIII Annex

* + 1. 本规定由研发部负责解释与修订。

Article 25 This regulation is explained and revised by R & D department.

* + 1. 本规定自发布之日起施行。

Article 26 These Provisions shall enter into force as of the date of publish.