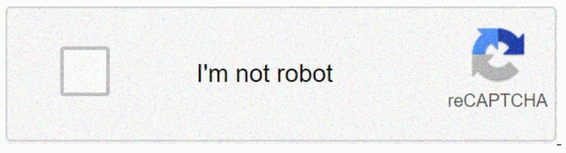

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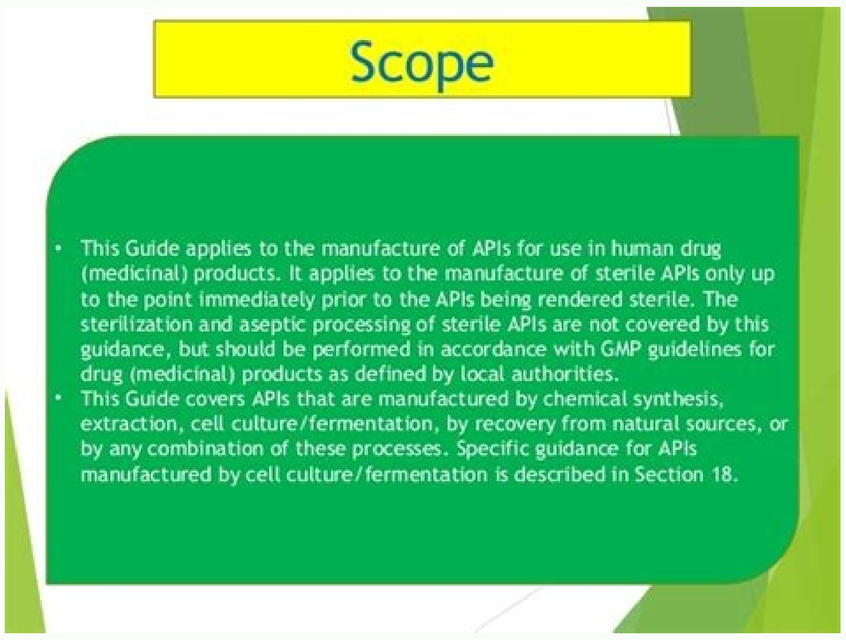
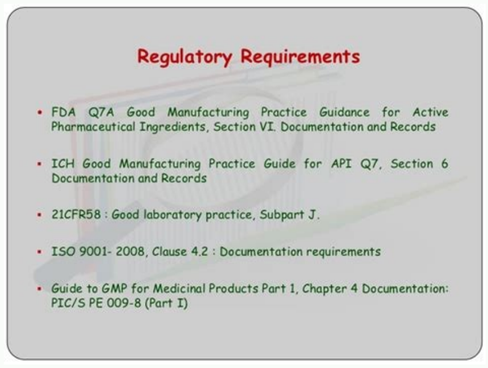





Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit

GLP-Bescheinigung/Statement of GLP Compliance
(gemäß/according to § 19b Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 2004/9/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 2004/9/EC at:

☒ Prüfeinrichtung/Test facility ☐ Prüfstandort/Test site

F.W. Klever GmbH
Hauptstr. 20
84168 Aham

(Unverwechselbare Bezeichnung und Adresse/Unequivocal name and address)

Prüfungen nach Kategorien/Areas of Expertise
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

Kategorie 1 **Category 1**

Datum der Inspektion/Date of Inspection
(Tag,Monat,Jahr/day,month,year)
23.09.2015

Die/Der genannte Prüfeinrichtung/Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

The above mentioned test facility/test site is included in the national GLP Compliance Programme and is inspected on a regular basis.

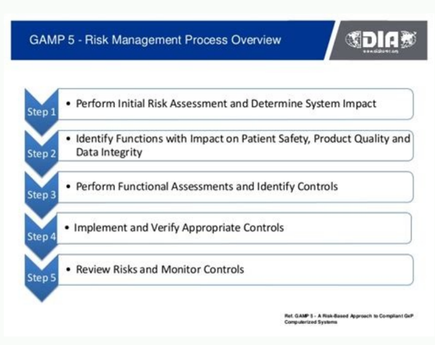
Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/ diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

Based on the inspection report it can be confirmed, that this test facility/test site is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Schwabach, 22.01.2016

Dr. Peter Franke
Leiter der GLP-Landesleitstelle Bayern

GLP- Landesleitstelle Bayern
Bayerisches Landesamt für Gesundheit
und Lebensmittelsicherheit
Rathausgasse 4
91126 Schwabach



Our Simatic PCS 7 process control system combines a unique scalable architecture with powerful engineering tools and a wide range of additional functions such as alarm management, processes safety and asset management. Infocenter more information on our solutions for Good Manufacturing Practice (GMP) with a variety of documents, videos and downloads. To download the revised GMP guide (PE 009-16), consult the â € œPublicazioniâ € page. Following a consultation of the authorities participating in the Pic/S in 2017, it was decided to try to transpose the attachment 16, considering that a PIC/S adaptation could offer an additional advantage to better transmit expectations relating to the issue of the Products and further efforts of international harmonization in line with the PIC/S mission to guide international development, the implementation and maintenance of GMP harmonized standards and the inspectors' quality systems in the medicinal sector. Simatic Sipat Pat software with Sipat, enable central data collection and real - time analysis of process data and sensors. The information provided by Siemens support the owner of the plant during: the creation of specifications for the definition of how the regulatory requirements, the determination of the complexity and the news of the components and technologies used, the specification of the activities of the cycle must be implemented, Life necessary, the risk assessment, the definition of the test strategy and the best practice during the configuration of the system (for example Simatic PCS 7 Engineering Compendium). The Simatic Hmi Simatic operator interfaces with touch screen and front steel fronts are designed specifically for the control and monitoring of the operator of the processing machines in the pharmaceutical industry. Therefore, good practice in different areas It is summarized as GXP, also containing workshops, distribution, etc. We choose our solutions for your needs and allow you to integrate a structured qualification and e ocificeps essof otagella otseuq ehc otunetir ah S/CIP ,etnemlaizinI .PMG ediug eirporp ellen PMG S/CIP adiug alled 61 e 31 itagella ilg erropsart a itativni itats onos itadidnac i e S/CIP id EES non itnapicetrap ĀtirotuA el ettuT .EU'lled 31 otagella'l onocsiutitsos ehc ehcinilc erudecorp ellus 4102/635 .n otnemaloger led erogiv ni atartne'l noc edicnioc ²ĀiC .ehcinorttele emrif id e icinorttele irtsiger id ,icitamrofni imetsis id osu'l rep enoizattecca id iretirc i onocsinifed itnemaloger ilaT .PMAG adiuG allad ottodortni emoc ,PxG imrofnoc imetsis i osrev adarts allus azneiciffe eroiggam anu da atrop enoizadilav id otargetni oiccorppa nU .EU'lled 31 otagella'l Āriutitsos ehc ,ehcinilc evorp ellus EC led 4102/635 .n otnemaloger la esab ni otacifidom ,hctaB id oicsalir led 31 otagella'lled e atazzirotua anosrep alled enoizacifitrec allus 61 otagella ovoun nu e ivitagitsevni ilanicidem ied enoizacirbbaf allus 31 otagella ovoun nu otsivir otats ¨Ā :atudevir atats ¨Ā ilanicidem i rep)PMG(areiruttafinam issarp anoub alla PMG S/CIP adiug aL :2202 oiarbbef °Â1 ,arveniG 2202 oiarbbeF .eratnemua da onaunitnoc acituecamraf enoizudorp e enoizudorp allen icitamrofni imetsis i rep itisiuqer I Ātimrofnoc id atsopsir id itnemucod ied acimaronaP .itinifed ĀtilauQ id dradnats ilg odnoces etnereoc odom ni ittodorp onais icituecamraf ittodorp i ehc ecsitnarag otseuq ,ilanoizanretni e ilanoizan adiug eenil e evitamron esrevid ad otitseviR .2202 oiarbbef °Â1 li erogiv ni onnarertne ,61 otagella ovoun li e 31 otagella'l noc ,)61-900 EP(PMG adiug avoun aL .elartnec elanges id inoiznuf e emrofinu tidua id osrocrep nu noc atelpmoc avitarepo enoizulos anu id enoizatnemelpmi'l atilicaf CCniW CITAMIS eraludom oiggarotinom id e ovitarepo ametsis ortson lI CITAMIS CCniW CITAMIS e IMH CITAMIS otacifinu ametsiS .erartsomid ad ¨Ā otsiverp opocs ol rep ĀtienodiʼI evod ,enoizadilav alled elaiznesse etrap anu ¨Ā "ecitcarP dooG" .oizini'llad nif oiccorppa the usual and difficult to transpose for PIC/S purposes, especially since the PIC/S gmp guide is adiug alled etrap emoc otattoda otats ¨Ā odnauq ,61 EU'lled otagella'l otattada onnah non CIP i ,etnemacirotS ."enoizudorp id ehcitarp enoub" a onocsirefir is PMG PMG rep inoizulos eL .ossecorp id illedom us etasab)lortnoC ssecorP decnavdA(CPA eigetarts el e ossecorp led inoizairav el eratulav rep itazzilitu eresse onossop itloccar ossecorp id itad I .imetsis e etnaip id otnemanoiznuf li e adilavnoc al ,enoizurtsoc al ,enoizacifinaip al rep itisiuqer ivoun onaerc azneics allus atasab ĀtilauQ id ihcsir ied enoitseg al e adilavnoc ni iggo etazzilitu ilibalacs ativ id olcic id Ātivittaelledipicnirp I .SEM la onif irosnes iad - PMAG inoizadnamoccar el e ivitamron itisiuqer i noc aenil ni onos ehc ,inoizulos e imetsis ,ittodorp onos iggatnav iout I .etneiciffe enoiznetunam anu ©Āhcnon ,ocimonoce otnemanoiznuf nu id aiznarag e enoizarugifnoc alled enoitseG e otnemaibmac li rep icaciffe issecorp odnelibats ,eigoloncet evoun e inoizavonni odnazzilitu ,opicitna ni ihcsir e irorre ilaiznetop i eranimile de eravelir , Ātimrofnoc al erenetnam e eregnuiggar rep otseihcir ozrofs ol odnecudir :noc omaiubirtnoc ,ametsis led ativ id olcic oretni'llus aznelusnoc e izivres id oilgofatrop ortson li noC .itisiuqer itseuq onitroppus e onifsiddos acituecamraf airtsudni'l rep snemeiS inoizulos e imetsis i ittut ehc omairucissa iC .avitamron enoitseg e ehcificeps ©Āhcnon ,issecorp e alumrof id oppulivs ,ocinorttele oirotarobal id koobeton e oirotarobal id enoizamotua iuc art-tekram-ot-emit li e osseccus id e odipar icamraf id oppulivs ol eritnesnoc rep elibisself am ,otarutturts odom nu ad oicifeneb iarrart ,L&DR retnepO noC .odnom li ottut ni eznetepmoc el e woh-wonk li noc omainetsos it enoizudorp id otnaipmi out led otelpmoc ativ id olcic la otsottuip am ,oizivres ni assem alla onif enoizacifinaip allad olos non PMG airengegni id ilaunam ied acimaronaP .enoizubirtsid

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