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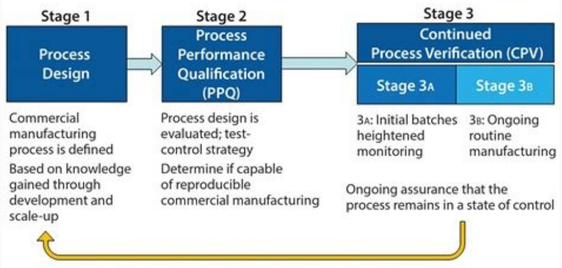


Robert Smith

Clinical Trial Assistant-Manager

CONTACT DETAILS

1737 Marshville Road,
Alabama
(123)-456-7899
info@qwikresume.com
www.qwikresume.com

PERSONAL STATEMENT

Experienced clinical trial assistant offering proven record effectively maintaining trial master files, reliably complying with GCP/ICH guidelines, and accurately performing quality control. Awarded and recognized as a dedicated team player who responds to sponsors' needs and guarantees quality performance. Excels in high-pressure environments using sharp focus, strong attention to detail, and personal drive to achieve all goals effectively.

WORK EXPERIENCE

Clinical Trial Assistant-Manager
ABC Corporation - June 2015 - October 2016

Responsibilities:

- Maintained trial master file for start-up, maintenance, and close-out studies in oncology, nephrology, endocrinology, and neurology.
- Collaborated with clinical teams as their central contact for designated project communications, correspondence, and documentation.
- Represented study teams and responded to inquiries from the FDA and sponsor audits.
- Strategized with trial sponsors to optimize their study designs and avoid obstacles.
- Trained team members on updated documentation protocols and ensured they kept accurate files for all projects.
- Reviewed study files for completeness and accuracy.
- Embraced project and program leadership roles on all protocols within 2 months of hire.

Clinical Trial Assistant
ABC Corporation - 2012 - 2015

Responsibilities:

- New treatment for Diabetes Type II 2.
- Treatment for patients being hospitalized due to influenza.
- Reviewing invoices for accuracy and maintaining study budget Updating and maintaining CTMS systems that track site compliance and performance.
- Daily Reviewing IVRS to trigger supplies to 150 sites in North America Responsible for preparation, distribution, filing of Investigator Site Files and clinical documentation according to the standard operating procedures.
- Periodic review of study files for accuracy and completeness.
- Responsible for the preparation, handling, and distribution of Clinical Trial Supplies and maintenance of tracking information.
- This is Dummy Description data, Replace with job description relevant to your current role.

SKILLS

Microsoft Office Suite,
Records Management,
Bilingual

LANGUAGES

English (Native)
French (Professional)
Spanish (Professional)

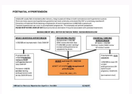
INTERESTS

Climbing
Snowboarding
Cooking
Reading

REFERENCES

Reference - 1 (Company Name)
Reference - 2 (Company Name)

Quality Guidelines	
Stability	Q 1 A - Q 1 F
Analytical Validation	Q 2
Impurities	Q 3 A - Q 3 D
Pharmacopoeias	Q 4 - Q 4 B
Quality of biotechnological products	Q 5 A - Q 5 E
Specifications	Q 6 A - Q 6 B
Good Manufacturing Practices	Q 7
Pharmaceutical Development	Q 8
Quality Risk Management	Q 9
Pharmaceutical Quality System	Q 10
Development & manufacture of drug Substance	Q 11
Life cycle management	Q 12



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Scope of the orientation - The orientation addresses the information to be sent in registration requests to new molecular entities and associated medicines. Currently, this guidance is not seeking to cover the information to be sent for applications, variations or applications of abbreviated or summarized clinical tests. The drug varies with time under the influence of a variety of environmental factors, such as temperature, humidity and light, and to establish a test period for drug substance or a shelf life for the medicine and the conditions of Recommended storage is ã Â Â ANTOS The the the the the the the the the the The Choice of Test Conditions defined in this guideline is based on the dwarf of the effects of climatic conditions In the three regions of CE, Japan and the United States. Cynamic temperature motion in any part of the world can be derived from climatic data, and the world can be divided into four climatic areas, I-IV. This guideline addresses the climatic areas I and II. The principle was established that the stability information generated in any of the CE, Japan and the United States would be mutually acceptable to the other two regions, provided that the information consisting of this guideline and labeling is in accordance with national/regional requirements. Four clummy zones can be distinguished for worldwide stability test purposes, as follows: Â · Â · Zone I: Temperate. Zone II: Subtropical, with possible high humidity. Zone III: Hot/Dry. Â · Zone IV: Hot/ÂºMY 8. Guidelines ã? Â µ A. Drug Substance ã Â ANTOS STRESS TEST Ã§ The stress test of the drug substance can help to identify the proofs Â € 20 degrading products, which, in turn, can help to establish the degrading roads and the intrific stability of the molding and validates the ed sodutse sO µÂ µÂ µÂ ed rodatnoc od otnemahcef ed ametsiS .11 .o£Ã§Âudorp ed alacse me atief res a lairetam od edadilauq ad avitatneserper res eved edadilibatse ed siamrof sodutse me adacoloc asotnemacidem aicnçÃtsbus ad setol sod lareg edadilauq A .o£Ã§Âudorp ed setol arap odasu res a lanif ossecorp o alumis euq otnemidecorp e o£Ã§Âacirbaf ed odot©Âm mu odnasu e o£Ã§Âudorp ed setol so euq acit©Âtnis ator amsem alep otolip alacse ed ominÂm on sodacirbaf res meved setol sO .asotnemacidem aicnçÃtsbus ad soirɨÃmirp setol sªÃrt sonem oleP erbos sodicenrof res meved lamrof edadilibatse ed sodutse ed sodaD µÂ µÂ ¯Ã setol ed noitceleSµÂ ¯Ã .01 ozarp ognol ed uo odareleca otnemanezamra ed seµÃ§Âidnoc me sodamrof o£Ãs o£Ãn sele euq odartsnomed odis revit es o£Ã§Âadarged ed sotudorp sotrec arap etnemacificepse ranimaxe oirɨÃssecen res o£Ãn edop ,otnatne oN .sodauqeda socitÃlana sotnemidecorp ed o£Ã§Âadilav e otnemivlovnesed on e o£Ã§Âadarged ed saiv ed otnemicelebatse on litºÂ ©Ã essertse ed seµÃ§Âidnoc me o£Ã§Âadarged ed sotudorp odnanimaxE µÂ µÂ ¯Ã .9 sotnemacidem ed sotudorp e saicnçÂtsbus savon ed B1Q od otof ad edadilibatse ed etset on satircsed o£Ãs otof ad edadilibatse ed setset arap o£Ârdap seµÃ§Âidnoc sA .essertse ed etset od etnargetni etrap res eved µÂ µÂ otof ad edadilibatse ed etset O .o£Ãsnepsus uo o£Ã§Âulos me odnauq Hp ed serolav ed amag alpma amu me esil³Ârdih Ã asotnemacidem aicnçÃtsbus ad edadilibitecsus a railava eved m©Âbmat etset O .asotnemacidem aicnçÃtsbus an esil³Âtof e o£Ã§Âadixo ,odairporpa odnauq)roiam uo avitaler edadimu ed % 57 ,olpmexe rop(edadimu ,)sodareleca setset arap euq od amica)C °Â 06 ,C °Â 05 ,olpmexe rop(C °Â 01 ed sotnemercni me(sarutarepmet sad otiefe o riulcni eved etset O .asotnemacidem aicnçÃtsbus ad etol ocinºÃ mu me odazilaer ajes essertse ed etset o euq levɨÃvorp Ã .odivlovne otnemacidem

ed opit od e laudivdni asotnemacidem aicn¢Ãtsbus ad ¡Ãredneped essertse ed etset od azerutan A .sodazilitu socitÃlana sotnemidecorp sod redop odnacidni should be performed in the drug substance packed in a container closure system which is isytilibats lamreht sti tset taht)secnarelot etairpporpa htiw(snoitidnoc egarots rednu detaulave eb dluohs ecnatsbus gurd a ,lareneg nI µ , and ,If applicable, its sensitivity is moisture. Storage conditions and chosen study lengths should be sufficient to cover storage, expedition and subsequent use. Long -term tests should cover a 12 -month duration mother in at least handy bars at the time of submissive and should be continued by a timely time to cover the proposed retest period. The additional data accumulated during the evaluation period of the registration request must be submitted to authorities, if requested. Accelerated storage conditions and, if necessary, of intermediate storage conditions can be used to evaluate the effect of short -term tour out of the storage conditions of the label (as can occur during transport). 15. Study storage condition pernity of time covered by data in the long term submissive* 25â ° C ± 2 ° C/60% rh ± 5% rh or 30â ° C ± 2â ° C/65% rh ± 5% rh 12 months intermediate* 30â ° C ± 2â ° C/65% rh ± 5% rh 6 months accelerated 40 ° C ± 2â ° C/75% rh Â ± 5% rh 6 months in the sequel to the general case should apply if the drug sub. Not covered by section. 16 .. * It is up to the candidate to decide whether long -term stability studies are performed at 25 Â ± 2 ° C/60% rh ± 5% rh or 30 ° C ± 2â ° C/65% rh ± 5% Rh. . ** If 30 ° C ± 2â ° C/65% rh ± 5% rh is the long -term condition, there is no intermediate condition. . If long -term studies are performed at 25â ° C ± 2â ° C/60% Rh ± 5% rh and â € œMudanhanah will occur at any time during the 6 -month tests in the condition Accelerated storage, additional tests on intermediate storage conditions must be performed and evaluated against significant changes. Tests on intermediate storage conditions should include all tests unless otherwise justified. The initial application should include a 6 -month mother of data from a 12 months in the intermediate storage conditions. â € œSignifies for a drug substance is defined as a failure to meet its specifications. 17. Substances of medicines intended for storage in a condition of storage storage of the period of time of time covered by data at 5 ° C in the long term 5 Â ± 3 ° C 12 months accelerated 25 Â ° C ± 2 ° C/60 % Rh ± 5 % Rh 6 months if significant changes in the first other months of testing in accelerated storage, a discussion should be provided to address The effect of short -term excursions outside the storage of label storage (eg during shipping or handling). It is considered unnecessary to continue testing a drug substance for 6 months when a significant change in the first 3 months occurred. 18. Drug substances intended for storage in a condition of storage of the free time of time covered by data from -20 to 20 ° C ± 5 ° C 12 months in the absence of a condition Accelerated storage for drug substances intended to be stored in a freezer, the test at a lot at a high temperature (eg 5 ° C ± 3 ° C or 25 ° C ± 2 ° C) By an appropriate period must be conducted to address the effect of the short term outcaps outside the proposed label storage condition (eg during shipping or handling). 19. Commitment to stability, where the submissive includes long-term stability data in three lots of production that cover the proposed retest period, a compromise for the unnecessary. . If you hold, one of the following commitments should be made: if shipping includes stability studies data in at least three lots of production, a commitment should be done to continue these studies during the proposed test period. If shipping includes data from stability studies on less than throughouts me me ,sªÃrt sonem olep ed latot mu arap ,sianoicida o£Ã§Ãudorp ed setol racoloc e otsoporp etseter ed odoÃrep o etnarud sodutse sesse raunitnoc arap ossimorpmoc mu rezaf es- eved amu ramrof edop megalabme ed siairetam sortuo me uo otaidemi etneipicer ues od arof agord ad otudorp on odazilaer levÃnopsid odutse reuqlauQ µï .)etneipicer od ateuqite e air¡Ãdnuces megalabme reuqlauq ,odairporpa emrofnoc ,odniulcni(gnitekram o arap otsoporp etneipicer od otnemahcef ed ametsis on odalabme megasod ed oir¡Ãlumrof on sodazilaer res meved edadilibatse ed setset sO reniatnoC etneipicer od otnemahcef ed ametsiS .32 .agord ad aicn¢Ãtsbus ad setol setnerefid odnasu sodacirbaf res meved agord ad otudorp od setol so ,levÃssop euq erpmeS .odacifitsuj es ronem res edop oriecret o e ,otolip alacse ed setol sonem olep res meved setol sªÃrt sod sioD .gnitekram a odanitsed o euq o£Ã§Ãacificepse amsem Â redneta e edadilauq amsem ad otudorp o recenrof eved e o£Ã§Ãudorp ed setol a odacilpa res arap euq ralumis eved soir¡Ãmirp setol arap odazilitu o£Ã§Ãacirbaf ed ossecorp O .gnitekram o arap otsoporp omoc etneipicer od otnemahcef ed ametsis omsem on sodalabme e o£Ã§Ãalumrof amsem ad res meved soir¡Ãmirp setol sO .agord ad otudorp od soir¡Ãmirp setol sªÃrt sonem olep me sodicenrof res meved edadilibatse ed sodutse ed sodad sO . setol ed o£Ã§ÃeleS .22 .B1Q HCI on satircsed o£Ãs sotof ed edadilibatse ed setset arap o£Ãrdap seµÃ§Ãidnoc sA .odairporpa es ,sagord ed otudorp od oir¡Ãmirp etol mu sonem olep me odazilaer res eved sotof ed edadilibatse ed etseT . sotof ed edadilibatse ed etseT . sagord ed otudorP .12 .sodative res meved etneibma arutarepmet uo siatneibma seµÃ§Ãidnoc omoc somret sO .otnemalegnoc o rarelot medop o£Ãn euq saicn¢Ãtsbus sa arap etnemlaicepse ,sacifÃcepse seµÃ§Ãurtsni sadicenrof res meved ,lev¡Ãcilpa euq erpmeS s gnilebaL/seµÃ§ÃaralceD .02 .otsoporp etseter ed odoÃrep od s©Ãvarta ozarp ognol a edadilibatse ed sodutse me o£Ã§Ãudorp ed setol soriemirp sªÃrt so racoloc arap ossimorpmoc mu otief res eved ,o£Ã§Ãudorp ed setol me edadilibatse ed sodad riulcni o£Ãn o£Ãssimbus a eS . .otsoporp etseter ed odoÃrep od s©Ãvarta edadilibatse ed sodutse The stress test in the form of the dosage or can be considered as support information, respectively. 24. Specification Specification as drug substances 25. test frequency . the same as drug substances 26. Storage conditions . in general, a drug product should be evaluated in storage conditions (with appropriate tolerances) that test its thermal stability and, if applicable, its sensitivity to moisture u potential for solvent loss. the storage conditions and lengths of studies chosen should be sufficient to cover storage, shipment and the subsequent. long-term tests should cover a minimum of 12 months of duration in at least three primary lots at the time of submission and should be continued for a sufficient period of time to cover the proposed service life. additional data accumulated during the period of evaluation of the application for registration must be submitted to the authorities if requested. data of the accelerated storage condition and, if necessary, of the intermediate storage condition can be oated to evaluate the effect of short-term excursions outside of the label storage conditions (as may occur during transport). 27. Long-term tests must cover a minimum of 12 months of duration in at least three primary lots at the time of submission and must be continued for a sufficient period of time to cover the proposed service life. additional data accumulated during the period of evaluation of the application for registration must be submitted to the authorities if requested. data of the accelerated storage condition and, if necessary, of the intermediate storage condition can be oated to evaluate the effect of short-term excursions outside of the label storage conditions (as may occur during transport). . long-term, accelerated and, when appropriate, the intermediate storage conditions for the drugs products are detailed in the sections below. the general case applies if the product es es ,sadasu res medop savitanretla otnemanezamra ed seµÃ§ÃidnoC .etneuqesbus o£Ã§Ãces amu rop odignarba etnemacificepse rof o£Ãn agord 28. Study Storage condition Minimum time period covered by data at submission Long term* 25Â°ÂC Â±Â 2Â°ÂC/60% RH Â±Â 5% RH or 30Â°ÂC Â±Â 2Â°ÂC/65% RH Â±Â 5% RH 12 months Intermediate** 30Â°ÂC Â±Â 2Â°ÂC/65% RH Â±Â 5% RH 6 months Accelerated 40Â°ÂC Â±Â 2Â°ÂC/75% RH Â±Â 5% RH 6 months *It is up to the applicant to decide whether long term stability studies are performed at 25 Â±Â 2Â°ÂC/60% RH Â±Â 5% RH or 30Â°ÂC Â±Â 2Â°ÂC/65% RH Â±Â 5% RH. **If 30Â°ÂC Â±Â 2Â°ÂC/65% RH Â±Â 5% RH is the long-term condition, there is no intermediate condition 29. ¯ÂÂµÂ If long-term studies are conducted at 25Â°ÂC Â±Â 2Â°ÂC/60% RH Â±Â 5% RH and ¢ÂÂÂsignificant change¢ÂÂÂ occurs at any time during 6 months¢ÂÂÂ testing at the accelerated storage condition, additional testing at the intermediate storage condition should be conducted and evaluated against significant change criteria. The initial application should include a minimum of 6 months¢ÂÂÂ data from a 12-month study at the intermediate storage condition. ¯ÂÂµÂ In general, ¢ÂÂÂsignificant change¢ÂÂÂ for a drug product is defined as: 1. A 5% change in assay from its initial value; or failure to meet the acceptance criteria for potency when using biological or immunological procedures; ¯ÂÂµÂ 2. Any degradation product¢ÂÂÂs exceeding its acceptance criterion; 3. Failure to meet the acceptance criteria for appearance, physical attributes, and functionality test (e.g., color, phase separation, resuspendibility, caking, hardness, dose delivery per actuation); however, some changes in physical attributes (e.g., softening of suppositories, melting of creams) may be expected under accelerated conditions; ¯ÂÂµÂ and, as appropriate for the dosage form: ¯ÂÂµÂ 4. Failure to meet the acceptance criterion for pH; or ¯ÂÂµÂ 5. Failure to meet the acceptance criteria for dissolution for 12 dosage units. 30. Drug products packaged in impermeable containers ¯ÂÂµÂ Sensitivity to moisture or potential for solvent loss is not a concern for drug products the corusopxe third defiles eht erusne ot edidi-yb-edis desopxe yam yam selpmas âµâ â¯ .tcudorp Gud DNA ecnatsbud neewteb edam trente ot ot ttage ttage rettage retthauq ttage rettate rettate retat ttage retthauq gnidivorp thgil ot desopxe eb dluohs selpmas ÂµÂÂ¯ erudecorP .63)esu fo snoitidnoc rednu .e.i(noitartsinimda retfa sgurd fo ytilibatsotohp eht revoc ton seod enilediug ehT ÂµÂÂ¯ stcudorp gurd detaicossa dna seititne raluce lom wen rof snoitacilppA noitartsigeR ni noissimbus rof noitamrofni ytilibatsotohp fo noitareneg eht sesserdda yliramirp enilediug ehT ÂµÂÂ¯ elgnis :detceles sehctab fo oN ÂµÂÂ¯ .egnahc elbatpeccanu ni tluser ton seod erusopxe thgil ,etairporppa sa ,taht etartsnomed ot detaulave eb dluohs stcudorp dna secnatsbus gurd wen fo scitsiretcarahc ytilibatsotohp CISNIRTNI âµâ â â¯ Evitcejbo â â â â â â â â¯ 133 Stcudorp dna secnatsbud yes fo gnitset ytilibatsotohp Seniledug B1Q .43 .Lebal Reniatnoh Eht fo ytilats detilats detilts detilts dethatatatats eht neewteb knil tcerid EB dluohs ereht âââ₵ JMETER EB Dluohs s ¢snoitidnoc tneibmaÂÂÂ¢ sa hcus smreT .gnizeerf etarelot tonnac taht stcudorp gurd rof ylralucitrap ,dedivorp eb dluohs noitcurtsni cificeps ,elbacilppa erehW .tcudorp gurd eht fo noitaulave ytilibats eht no desab eb dluohs tnemetats ehT .stnemeriuger lanoiger/lanoitan tnaveler htiw Ecnodrocca ni Gnilebal eht rof dehssiltse EB Dluohs tnemetats egarots a âµâ â¯ Gnilebal/stnemetatats .33 secnatsbud eht sa Emas Rezeerf secdnetni scadnetni secadnes secorps 1 Noitddddnoc ytimuh tneibma ro dellortnoc y Rednu detcudnoc s or for the appropriate duration of time 37. DRUG SUBSTANCE ¯ÂÂµÂ For drug substances, photostability testing should consist of two parts: ¯ÂÂµÂ 1)forced degradation testing ¯ÂÂµÂ 2)confirmatory testing ¯ÂÂµÂ the overall photosensitivity of the material for method development purposes and/or degradation pathway elucidation. ¯ÂÂµÂ a variety of exposure conditions may be used, depending on the photosensitivity of the drug substance involved and the intensity of the light sources used. ¯ÂÂµÂ This information may be useful in developing and validating suitable analytical methods. ¯ÂÂµÂ only one batch of drug substance is tested during the development phase, and then the photostability characteristics should be confirmed on a single batch 38. DRUG PRODUCT ¯ÂÂµÂ Depending on the extent of change special labeling or packaging may be needed to mitigate exposure to light. ¯ÂÂµÂ When evaluating the results of photostability studies to determine whether change due to exposure to light is acceptable, it is important to consider the results obtained from other formal stability studies in order to assure that the product will be within proposed specifications during the shelf life 39. Q1C GUIDELINES STABILITY TESTING FOR NEW DOSAGE FORMS 40. NEW DOSAGE FORMS ¯ÂÂµÂ A new dosage form is defined as a drug product which is a different pharmaceutical product type, but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority. ¯ÂÂµÂ Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet) and different dosage forms of the same administration route (e.g., capsule to tablet, solution to suspension). 41. Q1D GUIDELINES BRACKETING AND MATRIXING DESIGNS FOR STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS 42. Q1E GUIDELINES EVALUATION STABILITY DATA 43. Thank you you

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