Clinical Pharmacology & Biopharmaceutics

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The Main Components of Pharmaceutical Process Validation

Process Confrmation in Manufacturing of Biopharmaceuticals, Third Edition delves into the crucial aspects and current practices of process confrmation. It includes discussion on the fnal interpretation of the FDA 2011 Guidance for Assiduity on Process Validation Principles and Practices, generally appertained to as the Process Validation Guidance or PVG, issued in fnal form on January 24, 2011.

Introduction

e b k al ide g ideli e a d c e ace , a ell a cial ca e die ill a g he di e e a ache ha ca be ake f cce f l c ma fbi ha mace cal ce e .

Ca e die i cl de

² Npmacqq amlœpk_rgml dmp kck`p_lc afpmk_rmep_nfw

² sqgle ksjrgt_pg_rc_l_jwqgq rmmjq rm os_jgdw qa_jc+ bmul kmbcjq

² ? k_rpgv _nnpm_af dmp npmacqq amlœpk_rgml md _ ksjrgt_jclr bac e ial acci e [1]

² Q_largœa_rgml amlœpk_rgml dmp _ pckcbg_j kmlmajml_j _lrg`mbw cvnpcqqcb _lb `spgcb `w Afglcqc F_kqrcp Mt_pw &AFM' acjjq

² Tgp_j amlasppclac amlœpk_rgml qrsbgcq dmp _ npmbsar npmbsacb i a m al cell li e

Qwlrfcrga kcbgaglcq a_l `c ucjj af_p_arcpgxcb `w cqr_`jgqfcb jmega_j qrwjcq, @gmjmegaq ml rfc mrfcp f_lb _pc amknjcv* fgef+ kmjcasj_p+ ucgefr npmbsarq* _lb jmega_j qrwjcq f_tc jgkgrcb a_n_agrgcq rm dsjjw af_p_arcpgxc rfck _lb rfcgp amlr_kgl_rgml `gmep_nfgcq, Pcesj_rgml md `gmjmegaq glajsbcq lmr mljw œl_j npmbsar af_p_arcpgx_rgml `sr _jqm af_p_arcpgx_rgml _lb amlrpmjq ml p_u _aamsrpckclrq _lb rfc rfmqc k_lsd_arspgle npmacqqcq rf_r k_w `c a_sqgle t_pg_`gjgrw, ?jj ma fac i g ce [2].

?lmrfcp slbcpnglglle npglagnjc md npmacqq amlœpk_rgml gq rf_r os_jgrw _qqsp_lac qrp_rcegcq ksqr `c cpcarcb glrm c_af qr_ec md kcbgaglc ma fac i g ce .

e 3 hge f ce c ma a e

² Npmacqq Bcqgel - Ņc k_picr_`jc k_lsd_arspgle npmacqq gq de ed.

² Npmacqq Os_jgœa_rgml - Ņc bcqgel gq cqrgk_rcb rm bcrcpkglc ufcrfcp rfc npmacqqcq kccr rfc bck_lbq md pcnpmbsag`gjgrw,

² Slglrcppsnrcb Npmacqq Tcpgœa_rgml - Mlemgle _qqsp_lacq rf_r _jj ce e emai i a e fc l.

I im a e ha ma fac i g a d amk kcpag_jgx_rgml amlbgrgmlgle* k_lsd_arspcpq qfmsjb `c qsgr_`jc rm amlœpk rf_r rfc npmbsarq rf_r rfcw nj_l rm k_lgnsj_rc a_l kccr rfc pcosgpcb os_jgrw lmpkq _lb rf_r rfc bcqgelcb k_lsd_arspgle npmacbspcq a_l _aamk kmb_rc _srfmpgx_rgmlq pcj_rcb rm q_dcrw _lb cōa_aw Y1[,

K_lsd_arspcpq qfmsjb _jqm slbcpqr_lb gknjgagr t_pg_rgmlqgl ?argtc Nf_pk_acsrga_j amknmlclr &?NG' _lb kcbgaglc npmbsarq rf_r amsjb bm bspgle amk kcpag_jgx_rgml _lb qa_jc+ sn amlbgrgmlgle, Ņcw lccb . Clin Pharmacol Biopharm, 11 : 2 8 4.

he a ia [4].

Jgicugqc* _ nj_l rm amlrpmj dmp _lw t_pg_rgmlq rm qr_w ugrfgl DB? _srfmpgx_rgmlq gq cqqclrg_j,

e maj ideal al i de ig , d ce, a d mai ai he medici e ma fac i g ce d ce medici al ha mee he c ical a ib e f

² Gbclrgrw

² Qrpclerf

² Os_jgrw

² af_qrgrw

² Clcpew

Lccb cvncpr fcjn ugrf npmacqq amlœpk_rgml= Nmucp wmsp amk kgqqgmlgle* os_jgœa_rgml* _lb amlœpk_rgml mncp_rgmlq ugrf cbsa_rcb jgdc ugqbmk amDcpq Amk kgqqgmlgle* Os_jgœa_rgml $ amlœpk_rgml dpmk Ņc DB? Epmsn Y3[, Asppclr Emmb K_lsd_arspgle Np_argacq &aEKN' amkc cvnjmqgtcjw glrm nj_w ufcl qf_pgle gl nf_pk_acsrga_j npmacqq amlœpk_rgml amlbgrgmlgle, ? lsk`cp md rfck

gai g i g feedback ab d ma fac i g ac ce i c ical rm am k njg_lac ugrf aEKN,

² Ctclrs_jjw* aEKN _srfmpgx_rgmlq rf_r kcbgaglc+ k_lsd_arspgle glqr_jj_rgmlq _lb msrœr `c md pcqncar_`jc qgxc* amlqrpsargml*_lb nmqgrgml rm kccr lccbcb pcosgpc k clrq, Gr¦q lccbcb rf_r _jj msrœr `c _sbgrcb _lb a_jg`p_rcb _aampbgle rm _qqgbsgrw qncagœa_rgmlq Y6[,

S lbcpqr_lb_`jw* rfcpc _pc pcesj_rgmlq r_igle _rrcqr_rgml md upgrrcl ced e f d e a d ce c l ha a e ha d e f_tc rfc gbclrgrw* qrpclerf* os_jgrw* af_qrgrw* _lb clcpew rf_r rfcw¦pc e e e ed e i .

Qr_ec G - Npmacqq Bcqgel Pcamk kclb_rgmlq _lb npmqncarq

e mai ideal f ce de ig i de mi e he a licable ce f he ma ke able ma fac i g fa d e

² ?jrfmsef c_pjw npmacqq bcqgel rpg_jq bml¦r lccb rm `c ncpdmpkcb _aampbgle rm aEKN* rfcw qfmsjb `c amlbsarcb slbcp esgbcjglcq md d cie c i ci le .

Emmb _rrcqr_rgml np_argacq qfmsjb `c dmjjmucb, Gl n_prgasj_p* qrsbgcq ha a ed i e ha ceme f ce de a di g a e a ci a ed be ed.

² Lmlqrmn rcqrgle ?lb pc+rcqrgle _r rfgq qr_ec slrgj rfc npmacqq d_gjq gql¦r rwnga_jjw _lrgagn_rcb `w rfc DB?,

² Ņc cqr_`jgqf kclr md npmacqq amlrpmjq qcptcq rm glqspc npmbsar os_jgrw* _lb `w rfc q_kc rmicl _bbpcqq t_pg_`gjgrw gl rfc npmbsar, Ņc DB? cvncarq rf_r npmacqq amlrpmjq glajsbc cv_kgl_rgml md k_rcpg_j _q ella m i g.I a c la , ce c l a d m i g i c ical he

² Ņc npmbsar rp_gr gq cgrfcp lmr qclqg`jc mp cjqc kc_qsp_`jc &ce, kgapm`g_jgknspgrw',

² Mp ufcl npmbsarq glrcpacbc gql¼r ucjj+ af_p_arcpgxcb,

Qr_ec 0 Npmacqq Os_jgœa_rgml Pcamk kclb_rgmlq _lb npmqncarq

Ņc k_glgbc_jmd npmacqq os_jgœa_rgml gq rm bcrcpkglc gd rfc npmacqq bcqgel gq cDcargtc gl amk kcpag_jgx_rgml,

² ?nnjga_`jc bcqgel md rfc k_lsd_arspgle glqr_jj_rgml gq lccbcb slbcp aEKN_srfmpgx_rgmlq,

² Npmncp qcjcargml md kgjc_ec qwqrckq _lb msrœr rf_r _pc cpcarcb acc di g eeded de ig eci ca .

² Tcpgdwgle rf_r qwqrckq _lb msrœr mncp_rc ugrfgl lccbcb eci ca .

² Ņc npmacqq ncpdmpk_lac os_jgœa_rgml &NNO' amk`glcb glqr_jj_rgml* kgjc_ec* _lb msrœr ugrf bsjw rp_glcb j_`msp dmpac, Ņc DB? j_pecjw pcamk kclbq rf_r m`hcargtc kc_qspcq qgkgj_p _q qr_rgqrga_j apgrcpg_`cc knjmwcb ufclctcp nmqqg`jc,

² Upgrrcl npmrmamjq _lb _lrgagn_rcb gqqscq _pc tcpgr_`jw gknmpr_lr hi ge f ce c ma . l ec mme ded ha c lle , e rf_r lccb rm `c ncpdmpkcb* _lb qjgac nj_l Y7[, Npmqcasrgml md rfc NNO

`c sqcb `w _lw amk n_lw rm e_gl lmlqsncptgqmpw glRcvg`gjgrw* pcbsac rfc `spbcl _lb ejm`_j amk njcvgrw* _lb cl_`jc `pgqijw ncpncrp_rgml md _N?A dmp _bbgrgml md _ rcqrgle j_` rm _l `cgle rcqrgle nmglr* ugrfmsr _bbgle rfpc_r rm rfc a_qc _lb- mp npmbsar os_jgrw* q_dcrw* _lb cōa_agrw,

Acknowledgement

N e

Conflict of Interest

N e

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