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# Ispe Baseline Sterile Product Manufacturing Facilities

**quality risk management (qrm) - ispe-casa** - harm: damage to health, including the damage that can occur from loss of product quality or availability hazard: the potential source of harm (iso/iec guide 51) risk: the combination of the probability of occurrence of harm and the severity of that harm (iso/iec guide 51)  
**pharmaceutical utilities, current regulation ...** - pharmaceutical utilities, current regulation, qualification and validation. etif 2008. costa salguero centre - buenos aires - argentina. 24 october 2008 **facilities and equipment: cgmp requirements** - objectives • facilities and equipment cgmp highlights • aseptic manufacturing facility • equipment qualification • cleaning validation . quality production laboratory materials facilities ... **first class pharmaceuticals - gmpschoo** - validation master plan doc # vmp -001 version 1.0 june 2006 © first class pharmaceuticals pty ltd page 2 of 33 sign here after reviewing and approving the document ... **puritas capability statement 13nov13** - puritas pure solutions puritas pte ltd designers, suppliers & installers of specialist cleanrooms and controlled environments capability statement **regulatory considerations for antibody- drug conjugates** - regulatory considerations for antibody- -drug conjugates sarah pope mikinski, ph.d. (ondqa) marjorie shapiro, ph.d. (obp) ops, cder. aaps (october 18, 2012)  
**guidelines on validation appendix 5 validation of ...** - working document qas/16.667 page 3 90 background information 91 92 the need for revision of the published supplementary guidelines on good manufacturing 93 practices: validation (world health organization (who) technical report series, no. 937, 94 2006, annex 4) (1) was identified by the prequalification of medicines programme and a draft 95 document was circulated for comment in early 2013.

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