

## **WHO guidelines for Technology Transfer (TT):**

These guiding principles on transfer of technology are intended to serve as a framework which can be applied in a flexible manner rather than as strict rigid guidance. Focus has been placed on the quality aspects, in line with WHO's mandate.

1. Transfer of processes to an alternative site occurs at some stage in the life-cycle of most products, from development, scale-up, manufacturing, production and launch, to the post approval phase.

2. Transfer of technology is defined as “a logical procedure that controls the transfer of any process together with its documentation and professional expertise between development and manufacture or between manufacture sites”. It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party.

3. Literature searches revealed little information on the subject originating from national or regional regulatory bodies. Guidance on intra-company transfers was prepared by the International Society for Pharmaceutical Engineering (ISPE).

# WHO Guideline On Transfer Of Technology

**Roman Wölfel**

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## **Table of Contents Who Guideline On Transfer Of Technology**

1. Understanding the eBook Who Guideline On Transfer Of Technology
  - The Rise of Digital Reading Who Guideline On Transfer Of Technology
  - Advantages of eBooks Over Traditional Books
2. Identifying Who Guideline On Transfer Of Technology
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Who Guideline On Transfer Of Technology
  - User-Friendly Interface

4. Exploring eBook Recommendations from Who Guideline On Transfer Of Technology
  - Personalized Recommendations
  - Who Guideline On Transfer Of Technology User Reviews and Ratings
  - Who Guideline On Transfer Of Technology and Bestseller Lists
5. Accessing Who Guideline On Transfer Of Technology Free and Paid eBooks
  - Who Guideline On Transfer Of Technology Public Domain eBooks
  - Who Guideline On Transfer Of Technology eBook Subscription Services
  - Who Guideline On Transfer Of Technology Budget-Friendly Options
6. Navigating Who Guideline On Transfer Of Technology eBook Formats
  - ePUB, PDF, MOBI, and More
  - Who Guideline On Transfer Of Technology Compatibility with Devices
  - Who Guideline On Transfer Of Technology Enhanced eBook Features
7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Who Guideline On Transfer Of Technology
  - Highlighting and Note-Taking Who Guideline On Transfer Of Technology
  - Interactive Elements Who Guideline On Transfer Of Technology
8. Staying Engaged with Who Guideline On Transfer Of Technology
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Who Guideline On Transfer Of Technology
9. Balancing eBooks and Physical Books Who Guideline On Transfer Of Technology
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Who Guideline On Transfer Of Technology
10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
11. Cultivating a Reading Routine Who Guideline On Transfer Of Technology
  - Setting Reading Goals Who Guideline On Transfer Of Technology
  - Carving Out Dedicated Reading Time

12. Sourcing Reliable Information of Who Guideline On Transfer Of Technology
  - Fact-Checking eBook Content of Who Guideline On Transfer Of Technology
  - Distinguishing Credible Sources
13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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[120](#) [121](#) [122](#) [123](#) [124](#) [125](#) [126](#) [127](#) [128](#) [129](#) [130](#) [131](#) [132](#) [133](#) [134](#) [135](#) [136](#) [137](#) [138](#) [139](#) [140](#) [141](#) [142](#) [143](#) [144](#) [145](#) [146](#) [147](#) [148](#) [149](#) [150](#) [151](#) [152](#) [153](#) [154](#) [155](#) [156](#) [157](#) [158](#) [159](#) [160](#) [161](#) [162](#) [163](#) [164](#) [165](#) [166](#) [167](#) [168](#) [169](#) [170](#) [171](#) [172](#) [173](#) [174](#) [175](#) [176](#) [177](#) [178](#) [179](#) [180](#) [181](#) [182](#) [183](#) [184](#) [185](#) [186](#) [187](#) [188](#) [189](#) [190](#) [191](#) [192](#) [193](#) [194](#) [195](#) [196](#) [197](#) [198](#) [199](#) [200](#) [201](#) [202](#) [203](#) [204](#) [205](#) [206](#) [207](#) [208](#) [209](#) [210](#) [211](#) [212](#) [213](#) [214](#) [215](#) [216](#) [217](#) [218](#) [219](#) [220](#) [221](#) [222](#) [223](#) [224](#) [225](#) [226](#) [227](#) [228](#) [229](#) [230](#) [231](#) [232](#) [233](#) [234](#) [235](#) [236](#) [237](#) [238](#) [239](#) [240](#) [241](#) [242](#) [243](#) [244](#) [245](#) [246](#) [247](#) [248](#) [249](#) [250](#) [251](#) [252](#) [253](#) [254](#) [255](#) [256](#) [257](#) [258](#) [259](#) [260](#) [261](#) [262](#) [263](#) [264](#) [265](#) [266](#) [267](#) [268](#) [269](#) [270](#) [271](#) [272](#) [273](#) [274](#) [275](#) [276](#) [277](#) [278](#) [279](#) [280](#) [281](#) [282](#) [283](#) [284](#) [285](#) [286](#) [287](#) [288](#) [289](#) [290](#) [291](#) [292](#) [293](#) [294](#) [295](#) [296](#) [297](#) [298](#) [299](#) [300](#) [301](#) [302](#) [303](#) [304](#) [305](#) [306](#) [307](#) [308](#) [309](#) [310](#) [311](#) [312](#) [313](#) [314](#) [315](#) [316](#) [317](#) [318](#) [319](#) [320](#) [321](#) [322](#) [323](#) [324](#) [325](#) [326](#) [327](#) [328](#) [329](#) [330](#) [331](#) [332](#) [333](#) [334](#) [335](#) [336](#) [337](#) [338](#) [339](#) [340](#) [341](#) [342](#) [343](#) [344](#) [345](#) [346](#) [347](#) [348](#) [349](#) [350](#) [351](#) [352](#) [353](#) [354](#) [355](#) [356](#) [357](#) [358](#) [359](#) [360](#) [361](#) [362](#) [363](#) [364](#) [365](#) [366](#) [367](#) [368](#) [369](#) [370](#) [371](#) [372](#) [373](#) [374](#) [375](#) [376](#) [377](#) [378](#) [379](#) [380](#) [381](#) [382](#) [383](#) [384](#) [385](#) [386](#) [387](#) [388](#) [389](#) [390](#) [391](#) [392](#) [393](#) [394](#) [395](#) [396](#) [397](#) [398](#) [399](#) [400](#) [401](#) [402](#) [403](#) [404](#) [405](#) [406](#) [407](#) [408](#) [409](#) [410](#) [411](#) [412](#) [413](#) [414](#) [415](#) [416](#) [417](#) [418](#) [419](#) [420](#) [421](#) [422](#) [423](#) [424](#) [425](#) [426](#) [427](#) [428](#) [429](#) [430](#) [431](#) [432](#) [433](#) [434](#) [435](#) [436](#) [437](#) [438](#) [439](#) [440](#) [441](#) [442](#) [443](#) [444](#) [445](#) [446](#) [447](#) [448](#) [449](#) [450](#) [451](#) [452](#) [453](#) [454](#) [455](#) [456](#) [457](#) [458](#) [459](#) [460](#) [461](#) [462](#) [463](#) [464](#) [465](#) [466](#) [467](#) [468](#) [469](#) [470](#) [471](#) [472](#) [473](#) [474](#) [475](#) [476](#) [477](#) [478](#) [479](#) [480](#) [481](#) [482](#) [483](#) [484](#) [485](#) [486](#) [487](#) [488](#) [489](#) [490](#) [491](#) [492](#) [493](#) [494](#) [495](#) [496](#) [497](#) [498](#) [499](#) [500](#) [501](#) [502](#) [503](#) [504](#) [505](#) [506](#) [507](#) [508](#) [509](#) [510](#) [511](#) [512](#) [513](#) [514](#) [515](#) [516](#) [517](#) [518](#) [519](#) [520](#) [521](#) [522](#) [523](#) [524](#) [525](#) [526](#) [527](#) [528](#) [529](#) [530](#) [531](#) [532](#) [533](#) [534](#) [535](#) [536](#) [537](#) [538](#) [539](#) [540](#) [541](#) [542](#) [543](#) [544](#) [545](#) [546](#) [547](#) [548](#) [549](#) [550](#) [551](#) [552](#) [553](#) [554](#) [555](#) [556](#) [557](#) [558](#) [559](#) [560](#) [561](#) [562](#) [563](#) [564](#) [565](#) [566](#) [567](#) [568](#) [569](#) [570](#) [571](#) [572](#) [573](#) [574](#) [575](#) [576](#) [577](#) [578](#) [579](#) [580](#) [581](#) [582](#) [583](#) [584](#) [585](#) [586](#) [587](#) [588](#) [589](#) [590](#) [591](#) [592](#) [593](#) [594](#) [595](#) [596](#) [597](#) [598](#) [599](#) [600](#) [601](#) [602](#) [603](#) [604](#) [605](#) [606](#) [607](#) [608](#) [609](#) [610](#) [611](#) [612](#) [613](#) [614](#) [615](#) [616](#) [617](#) [618](#) [619](#) [620](#) [621](#) [622](#) [623](#) [624](#) [625](#) [626](#) [627](#) [628](#) [629](#) [630](#) [631](#) [632](#) [633](#) [634](#) [635](#) [636](#) [637](#) [638](#) [639](#) [640](#) [641](#) [642](#) [643](#) [644](#) [645](#) [646](#) [647](#) [648](#) [649](#) [650](#) [651](#) [652](#) [653](#) [654](#) [655](#) [656](#) [657](#) [658](#) [659](#) [660](#) [661](#) [662](#) [663](#) [664](#) [665](#) [666](#) [667](#) [668](#) [669](#) [670](#) [671](#) [672](#) [673](#) [674](#) [675](#) [676](#) [677](#) [678](#) [679](#) [680](#) [681](#) [682](#) [683](#) [684](#) [685](#) [686](#) [687](#) [688](#) [689](#) [690](#) [691](#) [692](#) [693](#) [694](#) [695](#) [696](#) [697](#) [698](#) [699](#) [700](#) [701](#) [702](#) [703](#) [704](#) [705](#) [706](#) [707](#) [708](#) [709](#) [710](#) [711](#) [712](#) [713](#) [714](#) [715](#) [716](#) [717](#) [718](#) [719](#) [720](#) [721](#) [722](#) [723](#) [724](#) [725](#) [726](#) [727](#) [728](#) [729](#) [730](#) [731](#) [732](#) [733](#) [734](#) [735](#) [736](#) [737](#) [738](#) [739](#) [740](#) [741](#) [742](#) [743](#) [744](#) [745](#) [746](#) [747](#) [748](#) [749](#) [750](#) [751](#) [752](#) [753](#) [754](#) [755](#) [756](#) [757](#) [758](#) [759](#) [760](#) [761](#) [762](#) [763](#) [764](#) [765](#) [766](#) [767](#) [768](#) [769](#) [770](#) [771](#) [772](#) [773](#) [774](#) [775](#) [776](#) [777](#) [778](#) [779](#) [780](#) [781](#) [782](#) [783](#) [784](#) [785](#) [786](#) [787](#) [788](#) [789](#) [790](#) [791](#) [792](#) [793](#) [794](#) [795](#) [796](#) [797](#) [798](#) [799](#) [800](#) [801](#) [802](#) [803](#) [804](#) [805](#) [806](#) [807](#) [808](#) [809](#) [810](#) [811](#) [812](#) [813](#) [814](#) [815](#) [816](#) [817](#) [818](#) [819](#) [820](#) [821](#) [822](#) [823](#) [824](#) [825](#) [826](#) [827](#) [828](#) [829](#) [830](#) [831](#) [832](#) [833](#) [834](#) [835](#) [836](#) [837](#) [838](#) [839](#) [840](#) [841](#) [842](#) [843](#) [844](#) [845](#) [846](#) [847](#) [848](#) [849](#) [850](#) [851](#) [852](#) [853](#) [854](#) [855](#) [856](#) [857](#) [858](#) [859](#) [860](#) [861](#) [862](#) [863](#) [864](#) [865](#) [866](#) [867](#) [868](#) [869](#) [870](#) [871](#) [872](#) [873](#) [874](#) [875](#) [876](#) [877](#) [878](#) [879](#) [880](#) [881](#) [882](#) [883](#) [884](#) [885](#) [886](#) [887](#) [888](#) [889](#) [890](#) [891](#) [892](#) [893](#) [894](#) [895](#) [896](#) [897](#) [898](#) [899](#) [900](#) [901](#) [902](#) [903](#) [904](#) [905](#) [906](#) [907](#) [908](#) [909](#) [910](#) [911](#) [912](#) [913](#) [914](#) [915](#) [916](#) [917](#) [918](#) [919](#) [920](#) [921](#) [922](#) [923](#) [924](#) [925](#) [926](#) [927](#) [928](#) [929](#) [930](#) [931](#) [932](#) [933](#) [934](#) [935](#) [936](#) [937](#) [938](#) [939](#) [940](#) [941](#) [942](#) [943](#) [944](#) [945](#) [946](#) [947](#) [948](#) [949](#) [950](#) [951](#) [952](#) [953](#) [954](#) [955](#) [956](#) [957](#) [958](#) [959](#) [960](#) [961](#) [962](#) [963](#) [964](#) [965](#) [966](#) [967](#) [968](#) [969](#) [970](#) [971](#) [972](#) [973](#) [974](#) [975](#) [976](#) [977](#) [978](#) [979](#) [980](#) [981](#) [982](#) [983](#) [984](#) [985](#) [986](#) [987](#) [988](#) [989](#) [990](#) [991](#) [992](#) [993](#) [994](#) [995](#) [996](#) [997](#) [998](#) [999](#) [1000](#)

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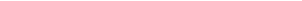
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