DRUG DEVELOPMENT

Hand 20 Dooks

Drug Development & Manufacture for Pharmaceutical Technology Professions

Drug Development Handbooks



© Copyright 1995 -2000 Locum International Ltd.

2001 Update Program

Part I and Part II: HandBook Generic Development Series

☑ Volume 1	Edition 03-01	✓ Volume 8	Edition 03-01
☑ Volume 2	Edition 03-01	✓ Volume 9	Edition 03-01
☑ Volume 3	Edition 03-01	☑ Volume 10	Edition 03-01
☑ Volume 4	Edition 03-01	☑ Volume 11	Edition 03-01
☑ Volume 5	Edition 03-01	☑ Volume 12	Edition 03-01
☑ Volume 6	Edition 03-01	☑ Volume 13	Edition 03-01
☑ Volume 7	Edition 03-01		

Initiation Date : December 2000 Expiration Date : December 2001

No of Years : One (1)

Update Period: December 2000, December 2001.

his Product is © Copyright 1992-2001 Locum International Ltd. has been updated to January 2001. It is available with a one (1) year regulatory update program which is wholly contingent on the customer preserving the copyright and initiating and maintaining membership of I.A.G.I.M. for the duration of the program and observing copyright conditions in full.

Update Licence No:

(See web site for IAGIM application membership form) info@iagim.org - http://www.iagim.org

Handbook of Pharmaceutical Generic Development

LICENSES: END-USER LICENSE AGREEMENT FOR LOCUM SOFTWARE & PUBLICATIONS

IMPORTANT READ CAREFULLY: This LOCUM End-User License Agreement ("EULA") is a legal agreement between you (either an individual or a single entity) and LOCUM Corporation for the LOCUM software product identified above, which includes "online" or electronic documentation and may include computer software and associated media and printed materials ("SOFTWARE PRODUCT" or "SOFTWARE"). By installing, copying, or otherwise using the SOFTWARE PRODUCT, you agree to be bound by the terms of this EULA. If you do not agree to the terms of this EULA, you are not authorised to use the SOFTWARE PRODUCT OR PUBLICATIONS.

SOFTWARE PRODUCT LICENSE

The SOFTWARE PRODUCT is protected by copyright laws and international popyright treaties, as well as other intellectual property laws and treaties. The SOFTWARE PRODUCT is idensed, not sold.

1. GRANT OF LICENSE. This EULA grants you the following rights:

Systems Software. You may install and use one copy of the SOFTWARE PRODUCT on a single computer. If the SOFTWARE PRODUCT includes functionality that enables your single computer to act as a network server, any number of computers or workstations may access of otherwise utilise the basic network services of that server. The basic network services are more fully described in the printed materials accompanying the SOFTWARE PRODUCT.

Storage/Network Use. You may also store or install a copy of the SOFTWARE PRODUCT on a storage device, such as a network server, used only to install or run the SOFTWARE PRODUCT on your other computers over an internal network; however, you must acquire and dedicate a license for each separate computer on which the SOFTWARE PRODUCT is installed or run from the storage device. A license for the SOFTWARE PRODUCT may not be shared or used concurrently on different computers.

· License Pack. If you have acquired this EULA in a LOCUM License Pack, you may make the number of additional copies of the computer software portion of the SOFTWARE PRODUCT authorised on the printed copy of this EULA, and you may use each copy in the manner specified above.

2. DESCRIPTION OF OTHER RIGHTS AND LIMITATIONS.

Limitations on Reverse Engineering, Decompilation, and Disassembly. You may not reverse engineer, decompile, or disassemble the SOFTWARE PRODUCT, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.

Separation of Components. The SOFTWARE PRODUCT is licensed as a single product. Its component parts may not be separated for use on more than one computer.

Rental. You may not rent or lease the SOFTWARE PRODUCT.

Software Transfer. You may permanently transfer all of your rights under this EULA, provided you retain no copies, you transfer all of the SOFTWARE PRODUCT (including all component parts, the media and printed materials, any upgrades, this EULA and, if applicable, the Certificate of Authenticity), and the recipient agrees to the terms of this EULA. If the SOFTWARE PRODUCT is an upgrade, any transfer must include all prior versions of the SOFTWARE PRODUCT.

- · Termination. Without prejudice to any other rights, LOCUM may terminate this EULA if you fail to comply with the terms and conditions of this EULA. In such event, you must destroy all copies of the SOFTWARE PRODUCT and all of its component parts.
- 3. UPGRADES. If the SOFTWARE PRODUCT is an upgrade from another product, whether from LOCUM or another supplier, you may use or transfer the SOFTWARE PRODUCT only in conjunction with that upgraded product, unless you destroy the upgraded product. If the SOFTWARE PRODUCT is an upgrade of a LOCUM product, you now may use that upgraded product only in accordance with this EULA. If the SOFTWARE PRODUCT is an upgrade of a component of a package of software programs that you licensed as a single product, the SOFTWARE PRODUCT may be used and transferred only as part of that single product package and may not be separated for use on more than one computer.
- 4. COPYRIGHT. All title and copyrights in and to the SOFTWARE PRODUCT (including but not limited to any images, photographs, animation, video, audio, music, text, and "applets," incorporated into the SOFTWARE PRODUCT), the accompanying printed materials, and any copies of the SOFTWARE PRODUCT, are owned by LOCUM or its suppliers. The SOFTWARE PRODUCT is protected by copyright

Handbook of Pharmaceutical Generic Development

laws and international treaty provisions. Therefore, you must treat the SOFTWARE PRODUCT like any other copyrighted material except that you may either (a) make one copy of the SOFTWARE PRODUCT solely for backup or archival purposes, or (b) install the SOFTWARE PRODUCT on a single computer provided you keep the original solely for backup or archival purposes. You may not copy the printed materials accompanying the SOFTWARE PRODUCT.

5. DUAL-MEDIA SOFTWARE. You may receive the SOFTWARE PRODUCT in more than one medium. Regardless of the type or size of medium you receive, you may use only one medium that is appropriate for your single computer. You may not use or install the other medium on another computer. You may not loan, rent, lease, or otherwise transfer the other medium to another user, except as part of the permanent transfer (as provided above) of the SOFTWARE PRODUCT.

6. U.S. GOVERNMENT RESTRICTED RIGHTS. The SOFTWARE PRODUCT and documentation are provided with RESTRICTED RIGHTS. Use, duplication or disclosure by the Government is subject to restrictions as set forth in subparagraph (c)(1)(ii) of the lights in Technical Data and Computer Software clause at DFARS 252.227-7013 or subparagraphs (c)(1) and (2) of the Commercial Computer Software Restricted Rights at 48 CFR 52.227-19, as applicable Manufacturer is LOCUM International GROUP LOCUM HOUSE ISRAEL.

Should you have any questions concerning this EULA, or if you desire to contact LOCUM for any reason, please contact the LOCUM subsidiary serving your country, or write: LOCUM Sales Information Center.

LIMITED WARRANTY

LIMITED WARRANTY. LOCUM warrants that (a) the SOFTWARE PRODUCT will perform substantially in accordance with the accompanying written materials for a period of ninety (90) days from the date of receipt, and (b) any hardware accompanying the SOFTWARE PRODUCT will be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of receipt. Some states and jurisdictions do not allow limitations on duration of an implied warranty, so the above limitation may not apply to you. To the extent allowed by applicable law, implied warranties on the SOFTWARE PRODUCT and hardware, if any, are limited to ninety (90) days and one year, respectively.

CUSTOMER REMEDIES. LOCUM's and its suppliers' entire liability and your exclusive remedy shall be, at Locum's option, either (a) return of the price paid, or (b) repair or replacement of the SOFTWARE PRODUCT or hardware that does not meet Locum's Limited Warranty and which is returned to LOCUM with a copy of your receipt. This Limited Warranty is void if failure of the SOFTWARE PRODUCT or hardware has resulted from accident, abuse, or misapplication. Any replacement SOFTWARE PRODUCT or hardware will be warranted for the remainder of the original warranty period or thirty (30) days, whichever is longer. Outside the United States, neither these remedies nor any product support services offered by LOCUM are available without proof of purchase from an authorized international source.

NO OTHER WARRANTIES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, LOCUM AND ITS SUPPLIERS DISCLAIM ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WITH REGARD TO THE SOFTWARE PRODUCT, AND ANY ACCOMPANYING HARDWARE, THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY HAVE OTHERS, WHICH VARY FROM STATE/JURISDICTION TO STATE/JURISDICTION. NO LIABILITY FOR CONSEQUENTIAL DAMAGES. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL LOCUM OR ITS SUPPLIERS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE OF OR INABILITY TO USE THE SOFTWARE PRODUCT, EVEN IF LOCUM HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. BECAUSE SOME STATES AND JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, THE ABOVE LIMITATION MAY NOT APPLY TO YOU.