

### Minimum system requirements

	REXS Server	REXS Client	About Client
System Version	Windows Server 2008 R2 or 2012R2	Windows 7, 8.1, 10 (32 or 64-bit)	A permanent network connection of at least 10Mbit/s is recommended. Microsoft Word & Excel (from 2010) and a PDF Reader are required for data export.
Hard Drive Space	350 MB	300 MB RAM	
Internal Memory	8GB at least	4GB at least	
	Microsoft .net Framework 4.5 full Profile or 4.7 (2012R2)	Microsoft .net Framework 4.5 or 4.7	
	Microsoft IIS Web services 7.5	-	
	Microsoft SQL Server 2008 R2 or higher (2014/2016)	-	

### Server Roles

Common http Features	Application Development	Health and Diagnostic	Security	Performance	Management Tools
Static Content	ASP.NET	http Logging	Windows Authentication	Static Content Compression	IIS Management Console
Default Document	.NET Extensibility	Logging Tools	Request Filtering	Dynamic Content Compression	IIS Management Scripts and Tools
http Errors	ISAPI Extensions	-	-	-	Management Service
http Redirection	ISAPI Filter	-	-	-	-

### Licenses and licence model

**REXS** is using a concurrent user licence model. The server licence is tied to the Fully Qualified Domain Name (FQDN) of the server. Only one server installation is allowed per acquired server licence. The licensing of the clients is based on concurrent user licences, which are provided by the server.

### System languages and time-related data

The system languages are German and English and can be changed at any time. Time-related data are saved in the database in UTC and are displayed in the current system time of the **REXS** client computer.

### Authentication and authorisation

For authorisation users are added to **REXS** by the customer. Users authenticate themselves via an Active Directory (AD) account. Therefore they can use their AD-password also in **REXS**.

### Evaluation

With the evaluation package, VTU offers the opportunity to test **REXS** before purchase.

### Programme documentation

As programme documentation, the user handbook and short user-guides are handed over in digital format.

### Implementation and training

The database installation can be done by the customer or by VTU via remote maintenance. This presupposes that VTU receives access to the customer server during the installation of **REXS**.

VTU offers **REXS** administrator training as well as user training courses and provides telephone support. In addition, VTU can offer training and consultancy concerning analysis and implementation of risk management processes.

### Maintenance and support

Support and software-maintenance for **REXS** is already included in the purchase price for the first year.

From the second year of application, VTU offers the opportunity to sign a maintenance contract. In which the update frequency for **REXS** is defined.

The VTU support team in Austria carries out maintenance, service and support. The technical support by VTU includes telephone or written user support (via e-mail).

### Development

The development of the **REXS** software is carried out in-house following predefined software development and documentation standards based on **EN ISO 9001**.

Software development follows the SCRUM model and is performed in a very close cooperation between VTU risk management experts and VTU software developers. Around ten experienced and highly qualified VTU employees are involved in the requirements engineering, programme development and testing of **REXS**.

Visual Studio is used as the development environment. Thanks to the internal VTU use of **REXS** in many VTU projects and the **REXS** support by experienced VTU employees a quick processing of programme errors as well as a high level of system usability is guaranteed.

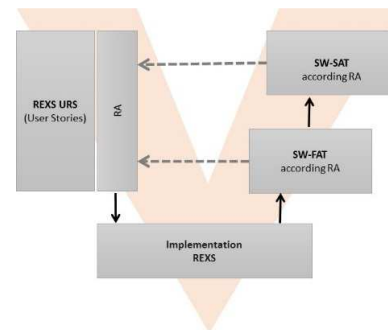
### Validation of REXS

The **REXS** software is classified according to **GAMP 5** (Good Automated Manufacturing Practice Guide) as category 3 software.

According to GAMP category 3 VTU makes the following validation documentation available:

- URS - user requirements specification including a risk assessment to define the extent of validation
- FAT - factory acceptance test protocol and report
- SAT - site acceptance test protocol and report

A validation according to customer-specific requirements can be additionally offered by VTU.



### References

For some years, **REXS** is used by VTU to assist experts during GMP- and safety risks assessments. In addition, VTU's project risks assessments are carried out by using **REXS**.

REXS references:

- Fresenius Kabi Graz
- Fresenius Kabi Oncology Ltd. India
- Boehringer Ingelheim
- Harro Hoefliger Verpackungsmaschinen GmbH
- Biotest AG
- TEVA Biotech GmbH