VALIDATION PLAN

FOR

ADVANEX EUROPE

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DOCUMENT CONTROL

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1. INTRODUCTION
   1. Objectives

The objectives of this Validation Plan are to provide a structured approach to

* 1. Associated documents

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Table 1.2: Associated documents.

* 1. Scope
  2. Equipment / Process

1. ORGANIZATIONAL STRUCTURE

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Table 2.0: Organizational structure.

1. STRATEGY AND STRUCTURE OF ACTIVITIES
2. CHANGE CONTROL
3. TERMS AND ABBREVIATIONS

*AEU-* Advanex Europe Ltd.

*IRA* -Initial risk assessment.

*URS –* User requirements specification.

*VP –* Validation policy

*AAM –* Advanex Americas.

*PE –* Production Engineering

*DE-* Design Engineering

*OP-* Operations

*PM –* Project Manager

*QA- Quality Assurance*

*SOP- Standard Operating Procedure*