



**NEW PROCESS**

**Development and  
Manufacturing of**

*Plasmid  
DNA*

**Richter-Helm** offers development and manufacturing services for Plasmid DNA.

With more than 20 years of experience, a well established quality assurance system and a new process Richter-Helm offers a variety of services to its clients:

#### **Manufacturing Process:**

- Unique proprietary technology
- High yield & quality
- Fast, robust, scalable
- Freedom to operate

#### **Additional Services:**

- Establishment and optimisation of host strains
- Manufacturing of GMP Cell Banks (MCB/WCB)
- Continual regulatory guidance
- ICH conform stability studies
- Formulation studies

#### **Experience:**

- Material from Tox to Phase III
- Manufacturing of material acc. to international standards e.g. EU/US/Japan

#### **Target Specifications:**

- Concentration: 0,1-10mg pDNA/mL (+/-10%)
- Purity: OD 260/280nm  $\geq 1,8$
- Purity: Clear colourless solution
- Homogeneity  $\geq 90\%$  ccc
- E.coli host DNA:  $\leq 10\mu\text{g}$  gDNA/mg ( $\leq 1\%$ )
- E.coli host RNA:  $\leq 20\mu\text{g}$  RNA/mg ( $\leq 2\%$ )
- E.coli host protein:  $\leq 10\mu\text{g}$  protein/mg ( $\leq 1\%$ )
- E.coli host endotoxins:  $\leq 10\text{EU/mg}$

*nonGMP / GMP*

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