

# Beneficial Microbes

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## Pharmaceutical like validation of a probiotic dietary supplement for kidney health

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The probiotic dietary supplement market is growing globally at 9.6%, with sales expected to reach 2.10 billion USD by 2015. Newer applications are growing from lowering cholesterol and boosting immunity, to anxiety, allergy and autism. However, there is none targeting kidney health. Renadyl™ was developed over a ten year period to reduce serum uremic toxins and impart a better quality of life to kidney failure patients. Extensive *in vitro* experiments and simulator of human intestinal microbial ecosystem (SHIME) studies led to a formulation consisting of *Staphylococcus thermophilus* (KB19), *Lactobacillus acidophilus* (KB27) and *Bifidobacterium longum* (KB31), which could reduce uremic toxins. Animal studies followed using 5/6<sup>th</sup> nephrectomised rats, mini-pigs, chronic kidney disease (CKD) cats and dogs. Subsequently, a randomised double blind placebo controlled crossover trial in CKD 3/4 patients was carried out using a dose of  $90 \times 10^9$  cfu/day at 4 sites, and an open label dose escalation study at  $90 \times 10^9$ ,  $180 \times 10^9$  and  $270 \times 10^9$  cfu/day. Another double blind placebo controlled crossover study with haemodialysis patient was recently completed with a dose of  $180 \times 10^9$  cfu/day. Outcomes were compared by measuring various uremic toxins, inflammatory biomarkers, faecal analysis and quality of life. Improvement in quality of life, reduction in levels of blood urea nitrogen, creatinine, C-reactive protein and indoxyl glucuronide was seen. Consumer acceptance of probiotics as dietary supplements will depend on major human clinical product validation as described.

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