

secure layer bonding, long lasting

During a modernisation project of its production facilities, a pharmaceutical manufacturer looked for new solutions for its pharma hose assemblies. Compared to existing hoses, longer service life, increased mechanical stability and easier cleaning were required. After extensive testing, the decision was made in favour of the new ELAPHARM®, developed by Elaflex.



*ELAPHARM hose assemblies in three versions:
with black or light grey cover (to DIN 26055-3 Type B, electrically conductive) and blue cover (to DIN 26055-3 Type A, electrically isolating)*

Apart from their suitability for a broad range of ultra clean media, hose assemblies for pharmaceuticals must be able to permanently resist the demanding CIP (Cleaning in Process) and SIP (Steaming in Process) cleaning methods. As batch production cycles increase at faster rates, the consequent cleaning process cycles are increased as well. The resulting high stress on equipment often has a negative impact on the lifetime of the hose assemblies.

_Problem: Service Life of Hose Assemblies
In the production plant of BERLIN-CHEMIE in Berlin Adlershof and Britz, Germany, approxi-

mately 100 different types of pharmaceuticals are produced. A multitude of various manufacturers hoses were in operation. "We had problems with the previously used hoses, therefore we tried several new types and brands. Until last year, the service life was generally unsatisfactory", says Marco Raböse, Manager of the Pharma Sterile Produktion Section of BERLIN-CHEMIE. In the course of modernising and reorganising our plant, he looked for new and more suitable pharma hoses to meet his demanding requirements.

Among others, one problem in particular was the transfer of powdery / crystalline products

via a vacuum tank to a batching tank. Hose constructions with loose (not bonded) layers led to a poor kinking resistance, and therefore to short replacement intervals and costly downtime.

The requirements for their hose assemblies had to be defined. The wish list included a hose where the constructional layers were homogeneously bonded together, absolutely smooth PTFE Liner and good resistance to pressure and vacuum service. The plant is regularly CIP and SIP cleaned, hence the need for the hoses to be able to withstand high temperatures and show a good reaction in relation to rapid hot/cold

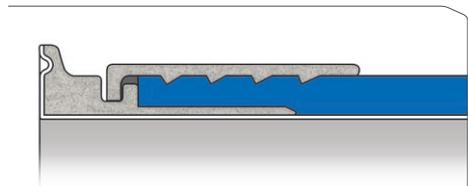
temperature changes. For media purity and due to constant changes of the transferred product, the fittings were required to be totally free of dead spaces. Last not least, FDA and USP Class VI conformity of the PTFE lining coming into contact with the media was taken as a minimum requirement.

_Solution: ELAPHARM Hose Assemblies

In 2013, Elaflex presented the ELAPHARM®, a new generation hose for pharmaceuticals to DIN 26055-3 (EN standard under preparation). The philosophy is that the hose layers are permanently bonded to each other. All layers, including the liner of DuPont Teflon® PTFE, are homogeneously bonded to each other. At the same time, a patented assembling process provides the possibility that the liner can be exposed and subsequently flared to achieve a passage free of dead spaces. The combination of both requirements is new.

The homogeneous hose construction leads to excellent kink resistance, pressure and vacuum resistances and longer operational life - without losing necessary flexibility. "This pharma hose fully comes up to our expectations for service life", says Marco Raböse explaining his decision for ELAPHARM hose assemblies.

Both the white and the black electrically conductive PTFE Liner conform to FDA guideline 21 CFR 177.1550 and CFR 178.3297 as well as USP Class VI and fulfill the requirements of EU regulations No. 1935/2004 and No. 10/2011.



Crimping 'free of dead spaces/flared'

_Fittings: free of dead spaces or gap minimised

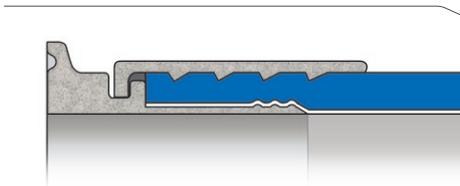
For ELAPHARM, Elaflex offers two types of crimped fittings. A) For highest media purity requirements, the manufacturer offers the 'free of

dead spaces / flared' method - i.e. with clamps to DIN 32676, M-conical couplings to 11851 and flanges. B) For less demanding applications in the pharmaceutical industry, Elaflex offers the 'gap minimised' method where the hose coupling is flush-mounted with the hose tail - this method is suitable for all coupling types.

ELAPHARM hoses are produced in lengths of approx. 40 metres. Hose assembling to customer specification is done in-house, straight from the reel. This enables short lead times, including pressure tests and material certificates being produced. If standard couplings are chosen, urgent orders can sometimes be supplied within a few days. The fittings can also be allocated their own unique reference detail which is permanently laser etched onto the hose sleeve.

_Test Applications

Spending testing time is well rewarded. Since the production launch in 2013, ELAPHARM has been tested internationally by various pharmaceutical manufacturers, in all cases results were positive. Examples of tested applications have been production of pharmaceutical ingredients, preparation of CIP media, bottling of tinctures and manufacture of infusion solutions. Since ELAPHARM has now been specified by several companies, Elaflex have commenced series production of the hose.



Crimping 'gap minimised'

The product has also been accepted for use in the BERLIN-CHEMIE manufacturing plant. Since May 2013 the electrically isolating Type EPH with blue cover and white PTFE liner has been in use. "We particularly value the highest pos-



BERLIN-CHEMIE: operator with the new, electrically conductive ELAPHARM with grey cover

sible workplace safety standards. The hoses are ready-assembled and supplied with all necessary documents. It's easy cleaning and handling argues for ELAPHARM. Also considering durability, the hose comes up to our expectations", Marco Raböse confirms. It was declared the new standard hose for the sterile production at BERLIN-CHEMIE.

_New: ELAPHARM OHM with Grey Cover

Customer requirements for a light colour cover in combination with full OHM (Ω/T) conductivity - not only conductive between hose ends but also through the wall, from the outside to the inside layer - have been acknowledged. Therefore Elaflex developed ELAPHARM-OHM hoses with a light grey cover. It may be used in EX-zones.

All three types, blue cover isolated and black and grey cover OHM, are available in seven sizes, DN 13 to 50 mm.

The company **BERLIN-CHEMIE AG** is a manufacturer of pharmaceuticals with long tradition and a dynamic business development. Its history dates back to 1890.

Today the company is owned by Menarini Group, the largest Italian Medicals Company with headquarters in Florence.

The production facility in Berlin -

Adlershof und Britz - produce solid pharmaceutical formulations (tablets, coated tablets and capsules), Liquida (mixtures and aqueous fluids), suppositories as well as infusion solutions.

End of 2013 the group employed around 5.450 people internationally and produced 385 million packages of ready to use medicals.

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Further Details:
http://www.elaflex.de/dokumente/download/ELAFLEX_Information_3.13E.pdf